STEM CELL RESEARCH AND EXPERIMENTATION IN INDIA: MAPPING PRACTICE AND POLICY

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DECLARATION

I hereby declare that this thesis entitled "**STEM CELL RESEARCH AND EXPERIMENTATION IN INDIA: MAPPING PRACTICE AND POLICY**", submitted to Jawaharlal Nehru University for the degree of Doctor of Philosophy, is my original work. This thesis has not been previously submitted for the award of any other degree of this or any other university.

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CERTIFICATE

We recommend that the thesis be placed before the examiners for evaluation and consideration of the award of Degree of Doctor of Philosophy.

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For those who live with disability and illness

Contents

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Abbreviations

ABLE	Association of Biotechnology Led Enterprises
AIIMS	All India Institute of Medical Sciences
ART	Assisted Reproductive Technology
BCIL	Biotech Consortium India Limited
BIPP	Biotechnology Industry Partnership Programme
CDSCO	Central Drugs Standard Control Organisation
CGHS	Central Government Health Scheme
CIOMS	Council for International Organisations of Medical Sciences
CP	Cerebral Palsy
CRO	Contract Research Organisation
CT	Computed Tomography
CTRI	Clinical Trial Registry of India
DBT	Department of Biotechnology
DCGI	Drugs Controller General of India
DST	Department of Science and Technology
EMI	Electric & Musical Industries
FDA (U.S.)	Food and Drug Administration
GOI	Government of India
hESC	Human Embryonic Stem Cell
HGP	Human Genome Project
HSC	Hematopoietic Stem Cell
ICMR	Indian Council of Medical Research
IC-SCR	Institutional Committee for Stem Cell Research
IEC	Institutional Ethics Committee
IMA	Indian Medical Association
inSTEM	Institute for Stem Cell Biology and Regenerative Medicine

iPSC	Induced Pluripotent Stem Cell
IUD	Intra Uterine Device
IVF	In Vitro Fertilisation
LPA	Little People of America
MD	Muscular Dystrophy
MND	Motor Neuron Disease
MS	Multiple Sclerosis
NCAER	National Council of Applied Economic Research
NCBS	National Centre for Biological Sciences
NCR	National Capital Region
NHS (U.K.)	National Health Services
OECD	The Organisation for Economic Co-operation and Development
RCT	Randomised Control Trial
SCNT	Somatic Cell Nuclear Technology
SRMTE	Society for Regenerative Medicine and Tissue Engineering
STS	Science and Technology Studies
TOI	Times of India
TPE	Therapeutic Plasma Exchange
TRIPS	Trade Related Intellectual Property Rights
UCB	Umbilical Cord Blood
USPHS	United States Public Health Service
WMA	World Medical Association
WTO	World Trade Organisation

Introduction

Stem cells have unique properties that could, in the future, offer therapeutic options for a range of currently incurable conditions. Since 1998, when developmental biologist, James Thomson announced the creation of the first human embryonic stem cell (hESC) lines[1], stem cell research has belonged to the world of politics, markets, the public and the media, as much as it has to the domain of cutting edge science (Thomson *et al* 1998). While many of the fundamental workings of stem cells remain elusive to researchers, the extraordinary entities have been co-opted by economic agendas of governments and into the everyday discourse on hope of ordinary people. Today, the only established or clinically proven stem cell treatment is of the haematopoietic stem cell, found in the blood system, and used for blood disorders or certain autoimmune conditions[2] (Australian Stem Cell Centre 2011). Stem cell treatments or therapies of any other kind are considered experimental[3], and yet to be scientifically proven for safety and effectiveness in patient use. This thesis, based on a qualitative study, argues that experimental stem cell treatments were routinely offered in India's health system and the practice was also normalised in the daily lives of middle class patients, in mostly urban settings across India. The study analyses the different routes of normalisation and the various forces at play that made medical experimentation seem regular and an inevitable therapeutic choice. The study also finds that a new kind of experimental population has emerged in the process of normalisation—the middle class subject. The micro engagements of these subjects with unproven stem cell treatments were embedded within the larger context of a contemporary consumer culture and were not dissimilar to other practices that defined them as middle class (Fernandes and Heller 2006). The term middle class or "new middle class" in India today, although variously understood, is widely argued in literature as a product of India's economic liberalisation of the 1990s (Fernandes and Heller 2006:495). New state policies at this juncture gained legitimacy by offering greater opportunity and wider consumer choice in health care, education,

[1] A cell line is a collection of healthy, undifferentiated or unspecialised cells. Thomson had successfully grown hECS lines in culture, without differentiation, for four to five months (Waldby 2002). At a certain point in "their developmental trajectory" in the human body, these cells would become "specialized tissues" (Waldby 2002:315)

[2] In the 1950s, scientists discovered two types of stem cells in the bone marrow: the haematopoietic stem cell and the mesenchymal stem cell. The latter gives rise to cell types like bone, cartilege and fat cells (National Institutes of Health, U.S. 2016).

[3] The term experimentation does not necessarily imply research, except when an experiment is "conducted for the purpose of developing generalizable knowledge" (Levine 1998:10). According to Levine the term " 'experiment' " means to test something or to try something out" (Levine 1998:10).

employment, leisure, media, travel and other services. It was in the promise of a better and brighter future offered by this market-oriented change in everyday life, that the middle class identity was constituted and a middle class life imagined, regardless of whether the future envisaged was real for those who aspired towards it. The pursuit of the desired goal, in other words, became as integral to being middle class as was the state of its fulfilment. The provision and use of stem cell treatments was easily incorporated into existing cultural notions and sites of possibility and choice, "whereby the new is always seemingly better" (Brown, Kraft and Martin 2006:330). The routes the respondents chose for seeking stem cell treatments were similar to the paths they would have pursued for other life wishes and goals. Experimenting with stem cell treatments, for both patient and provider, was thus not perceived as illogical or irrational but rather a natural response to another opportunity that had presented itself.

With the culturing of the first hESC lines, stem cell research was propelled into the public realm from the rarefied space of the laboratory, shaping and changing the meaning of stem cells in ways that perhaps even its innovators would not have imagined. Stem cells are unspecialised cells that have the capacity to differentiate into specialised tissue with specific functions. These cells can also self-renew themselves. Both properties of self-renewal and differentiation give stem cells the special quality of regenerating or replacing damaged or affected tissue and also, therefore, have the future potential to provide alternative solutions to organ transplants. Other than the human embryo, umbilical cord blood (UCB)[4] and bone marrow, the other sources of stem cells include the foetus and specific tissues of the adult body, such as skin, liver, brain, nose etc. (Australian Stem Cell Centre 2011). Current research shows that non-embryonic stem cells also known broadly as adult stem cells have limited capacity to differentiate into various cell types other than the tissue or organ of its origin, making the hESC the most coveted of all stem cells. The latter has the greatest power of pluripotency, implying the hESC potential to "become any one of the 220 or so different kinds of cell in the human body" (Sexton 2011:4). The ability to harness the fundamental, in-vivo property of a human embryonic stem cell in an artificial environment was, thus, no small feat performed by Thomson and his team at the University of Wisconsin in the U.S. Leading publications like *Science* described the efforts of these scientists as a "breakthrough" (Vogel 1999:2238). Eliot

[4] Cord blood (stem cell) transplants are "best established" for blood conditions. The first CB transplant was performed in 1986 in a case of Fanconi's anaemia, a "rare" genetic disorder (Dickenson 2008:52)

Marshall wrote about the development in the same issue of *Science* that featured the report by Thomson and his team. Marshall described how Thomson had successfully faced the "challenge" of creating the perfect "environment" for growing the cells: He "coaxed the balky cells to continue growing without differentiating—making an irrevocable commitment to grow into a particular type of tissue" (Marshall 1998:1014). The *Times of India* (*TOI*) also carried an article, "The Promise of Stem Cells", the year after the discovery (*TOI* 1999:A8). A collection of stable, self-dividing hECS cells in a laboratory had far reaching implications for basic research, "drug discovery, and transplantation medicine" (Thomson *et al* 1998:1145). When grown in a culture dish these cells could potentially "be induced on demand" to provide an "unlimited supply" of the particular tissue needed (Waldby 2002:306). There are several conditions caused by irreparable damage to nerves and cells, the affects of which are catastrophic, causing intractable disability and in some cases severely shortened life spans. If stem cells could offer cures they would, justifiably, be treated as nothing short of miracles for both patients and doctors. Parkinson's disease, Alzheimer's disease, spinal cord injuries, heart disease and neuromuscular conditions such as muscular dystrophy are among the long list of conditions that continue to confound and challenge medicine. Chronic diseases like diabetes, affecting millions the world over, are also included as targets for future stem cell therapies in the hope that the technology could produce insulin forming cells (Waldby 2002).

The culturing of hESC lines had followed close on the heels of another landmark event: the birth of Dolly, the cloned sheep. Born in the U.K., in 1997, Dolly's birth was the result of somatic cell nuclear transfer or SCNT, a biotechnology that also had implications for stem cell research. It involved the fusing of an adult cell with a de-nucleated egg cell, which was then reprogrammed to behave like an embryo and eventually gestated by a surrogate ewe. In 1999, Geron a U.S. based, pharmaceutical company bought the institute that produced Dolly with the intention of using SCNT technology to develop human stem cell lines. If successful, patients would be the source and recipient of adult cells making chances of tissue rejection, a major barrier to successful organ transplants less likely (Franklin 2001;Waldby 2002). Cloning technologies and stem cell research had captured the imagination of many at this time, but along with narratives of scientific progress there were also those of fear and doubt about what these could portend for future relationships between science and society (Franklin 2001). Could entire human beings be created with the new knowledge of cloning techniques was among many questions being raised. In

response to these concerns, the U.S. in 1997 restricted the use of cloning technologies to "therapeutic cloning" or cloning only parts of the body for producing clinical applications such as stem cell therapies (Franklin 2001:335). Ethical concerns were also raised about procurement of eggs for SCNT (Waldby 2008), and hESC research in the U.S. faced fierce opposition from pro-life groups that equated the destruction of embryos to the killing of entities in whom they ascribed a right to personhood (Gottweis, Salter and Waldby 2009). In 2001, the U.S. banned all federal funding for hESC research, restricting support to only those cell lines that were already in existence[5]. The controversy and simultaneous enthusiasm by which these medical technologies were received in sites of their innovation, resulted in a complex regulatory regime in hESC research the world over: from a complete ban in Ireland, to permitting the use of only imported embryos in Germany, to countries like the U.K. and India allowing embryos left over from in vitro fertilisation (IVF), or those not more than 14 days old (Waldby 2002, Gottweis, Salter and Waldby 2009). The relatively liberal position in the U.K. on hESC research was perceived as giving the nation considerable competitive advantage in the field (Franklin 2005). India too, had been placed on the global map of stem cell innovation. Among the 64 hESC cell lines that were still eligible for U.S. funding in 2001, ten were located in institutes in India. Three of the cell lines belonged to the National Centre for the Biological Sciences, a public sector institute and the rest were developed by Reliance Life Sciences, a private biotechnology firm in Mumbai (Bharadwaj and Glasner 2009).

In the past decade, India has attempted to build its own legitimate, globally accepted stem cell industry (Salter *et al* 2007). While the country is seen as a serious contender to the "traditional" leaders of biomedical research such as the U.K. and U.S. (Glasner 2009:284), it has also made national and global news for the unethical stem cell practices of its medical professionals (Bharadwaj and Glasner 2009). In 2007, India drafted its first national guidelines for "stem cell research and therapy" on similar lines to those adopted by the U.K. and U.S. (Department of Biotechnology and Indian Council of Medical Research 2007). Since then, the Department of Biotechnology (DBT) and the Indian Council of Medical research (ICMR), major actors in biotechnology policy, have held public consultations and produced a series of documents to ensure oversight of research on human subjects and stem cell

[5] In 2009, U.S. President Obama revoked the 2001 ban on hESC research in the country. This reversal in the law was not, however, without legal complications as U.S. courts and political opponents despite Obama's policy change have upheld the Dickey-Wicker amendment of 1995, a congressional bill that prohibited federal funds for any research in which embryos were " 'destroyed, discarded or knowingly subjected to risk of injury or death' " (Jasonoff 2005:179; Park 2011).

research in particular. The latest, 2017, guidelines for stem cell research define stem cells as " 'drugs' " to ensure that researchers follow only state approved ethical and scientific regulations for clinical trials (ICMR and DBT, GOI 2017:13). By adopting globally accepted standards for conducting biomedical research and providing stem cell treatment, India signalled to the world its commitment to curb a lax regulatory environment and its desire to secure a leading position within global networks of stem cell innovation and new biomedical markets (Bharadwaj and Glasner 2009). Both private and public sector institutions in India today conduct stem cell research using the entire range of stem cells. Basic research of any significance, however, takes place in public sector institutions[6]. In addition to supporting basic and clinical research, the DBT has planned stem cell city clusters, established departments and institutions for stem cell biology, enabled public-private partnerships in biotechnology, built scientific expertise, incentivised expatriate scientists to return to India and initiated regulatory and legal frameworks in compliance with international regimes (Salter *et al* 2007; Bhattacharjee 2008).

The interest of governments in stem cell research was "economically driven in a broad sense, with population health benefits and clinical applications assigned a secondary consideration", argued Gottweis and others (Gottweis, Salter and Waldby 2009:23). By the time of Thomson's discovery, the commercialisation of scientific research had been well consolidated through policy and law in countries like the U.S. A landmark judgment, in 1980, by the U.S. Supreme Court, declared a biological organism patentable creating further interest in industry in biomedical product development (Jasonoff 2005). The knowledge or information-based economy was increasingly replacing others sectors as the key driver of economic growth in advanced capitalist countries. Concepts such as "biovalue" and "biocapital" were developed by Waldby and Sunder Rajan, respectively, to analyse how human biology had taken centre stage as a source of capital and economic growth (Waldby 2002; Sunder Rajan 2006). The term "biocapital" intended to provide a conceptual structure to look at how science as a commercial enterprise developed in tandem "with political economic regimes", both impinging on, rather than determining each other (Sunder Rajan 2006:4). The "corporatization of the life sciences" stated Sunder Rajan, occurred because of certain favourable political and economic conditions, that in turn were also helped by the kind of scientific innovation taking place in these countries which lent itself to commercial opportunity (Sunder Rajan 2006:4).

[6] 70 percent of R&D funding in India is derived from public funds that includes state and central government sources (Bound 2007).

Scientific activity from the 1970s and 1980s had needed new analytical structures because biomedical innovation had begun to capitalise on life at the level of its "fragments" rather than the entire body, stated Waldby (Waldby 2002:309-310). A range of "biotechnical procedures" are being applied today to "make" biological entities such as "cells", genes, "eggs" "ever more productive" (Waldby 2002:309-310). This "yield of vitality produced by the biotechnical reformulation of living processes" is how Waldby defined "biovalue", the "incentive" for which, she stated was both health and wealth (Waldby 2002:310).

The very nature of new biomedical developments also changed existing ways in which research took place. For example, the "same stem cell line" can be frozen, stored and transported anywhere in the world (Gottweis, Salter and Waldy 2009:6). India has deposited two hESC lines at the U.K. Stem Cell Bank[7] and also imports cell lines for research purposes. Global networks such as these are a key feature of a knowledge economy. The networks are highly competitive but also built on "mutually beneficial" partnerships among science and industry — all of which require a favourable political regime for the easy movement of expertise, biological objects, information and capital (Gottweis, Salter and Waldy 2009:19). State support was also considered essential to assume some proportion of the risk involved with new technologies such as stem cells that were proving unpredictable in outcomes (Gottweis, Salter and Waldby 2009). India's participation in global networks of research and development were made possible by globalising policies adopted in the 1980s-1990s in various sectors of the Indian economy such as trade, health care, drug development, intellectual property and telecommunications. These structural changes facilitated biomedical research in the country and entry into markets for new technologies. By 2004, 75 percent of funding globally for stem cell research and hECS's in particular, came from government sources (Gottweis, Salter and Waldby 2009). Stem cells were, thus, not ordinary cells by any definition. They have occupied privileged positions in high-level gatherings, national policy debates and appeared prominently within national economic goals and aspirations of "global competitiveness" in the knowledge sector among nations the world over (Birch 2009:273). Since Thomson's creation of hESC lines, there have been other more recent and significant developments in the field, predominantly in adult stem cells. In 2006, Japanese scientist Yamanaka developed the induced pluripotent stem cell

[7] The Jawaharlal Nehru Centre for Advanced Scientific Research in Bengaluru, supported by the DBT, derived the hESC lines that have been deposited at the U.K. Stem Cell Bank. The Bank is a repository for cell lines for the global scientific community (Jawaharlal Nehru Centre for Advanced Scientific Research 2008).

(iPSC) from mouse models. The iPS cells were made pluripotent like the hESC, except, these were not embryonic cells but rather they were derived from the skin. Within months, Yamanaka and Thomson collaborated to use the same technology to induce pluripotency in human adult cells, giving them the potential to differentiate into various cell types like the hESC. The iPS cell, many believed, would "herald a medical revolution (Scudellari 2016:310). Derived from the patient's own body, iPS cells had the potential to provide a steady supply of pluripotent and "immunocompatible" treatments (Waldby 2002:321). Moreover, the technology was possible without eggs or embryos, which could render ethical and regulatory barriers as problems of the past. The iPS cells have, however, currently proven more useful for drug screening purposes than treatments due to risks of cancerous mutations similar to the hECS (Scudellari 2016).

Almost two decades after Thomson's discovery gave hope to millions of patients worldwide, the scientific barriers to producing new stem cell treatments have remained. In the face of these challenges it would seem prudent for governments and industry to divert their attention to other areas and reduce the rhetoric of global leadership in regenerative medicine markets but this has not been the case. An extensive scholarship has investigated the reasons for the sustained interest in certain kinds of new technologies despite their uncertain futures. Described as the "sociology of expectations", that also informs science and technology studies (STS), this body of work has investigated how hope was used by the biotechnology industry to create "value" in medical technologies that have not yet proven useful to patient, government or investor (Martin, Brown and Turner 2008:127). This value, with multiple meanings—emotional, financial and scientific—was defined by what can be, rather than what is positively known, to paraphrase Moreira and Palladino (Moreira and Palladino 2005:67). The biomedical industry had used hope (Martin, Brown and Turner 2008), as a way to "manage uncertainty", these authors argued (Brown and Michael 2003:4). The global success of the cord blood industry has exemplified this overwhelming influence of "promissory value" in mobilising commercial activity in stem cells (Sexton 2011:2). Stem cells in a single source of cord blood are found in insufficient quantities and the number of diseases that cord blood can currently treat is limited (Hodges 2013). Yet, private banks are less likely to draw attention to these current limitations of cord blood. They sell their services primarily on the promise of cord blood as the source of future cures for a range of unproven conditions (Martin, Brown and Turner 2008:130). In 2007, facts notwithstanding, there existed a "sizeable international" industry in private cord blood banking, showing annual

revenues of over 200 million U.S. dollars (Martin, Brown and Turner 2008:141). The industry also extended to "new promissory geographies in East Asia and Latin America" stated Martin and colleagues (Martin, Brown and Turner 2008:141). In 2013, India's private "stem cell banking industry" was valued at 200 crore rupees or 32 million U.S. dollars (USD), with projections evaluating it at 2700 crore rupees or 430 million USD by 2020 (Patra and Sleeboom Faulkner 2016:268). Hodges, in her analysis of the cord blood industry in the city of Chennai, in South India, described private banks using "glossy brochures and slick websites" featuring popular movie actors to encourage new clients (Hodges 2013:9). The "marketing offices" of these banks, she stated, were built with "chrome" and "glass", incorporating the stem cell into larger narratives of a globalised and modernised India, providing its citizens with new technologies to secure a future safe from disease (Hodges 2013:9). In contexts of advanced industrialised societies, Rose viewed 21st century techno-science as the harbinger of new opportunities for individuals to take control of their health and wellbeing (Rose 2007). Others argued, on the other hand, that the role of expectations in biomedical technologies was not "neutral" but rather permitted the enactment of only some futures (Brown and Michael 2003:4). By manoeuvring hope in specific directions, the biotechnology industry had legitimised the future in the present moment, mobilising different interest groups such as funders, scientists, patient organisations and also "macro level" actors through "regulation and research patronage" (Borup *et al* 2006:286). Scientists today continue to labour over the intricacies of stem cell research, and governments have extended their support in the hope that past successes will bring future benefits. Hope, as the "cause" and the "consequence" of "technological activity" was, thus, crucial to the survival of new biomedical markets and in maintaining systems within which a biotechnology was embedded (Borup *et al* 2006:286).

In foregrounding the role of expectations in new medical biotechnologies, these writings also drew attention to the inclusion of social dimensions in analysing science, thereby emphasising the contingent nature of technological development. The ways in which scientific knowledge is received and accepted cannot be viewed as separate "from other forms of social activity, but are integrated instead as indispensable elements in the process of societal evolution", said Jasonoff (Jasonoff 2004:17). In this statement lies the essential message of the STS tradition, that science does not determine its own fate but rather "science and society" are "*co-produced*" (Jasonoff 2004:17). The discipline argued for the recognition of the social or non-scientific world in investigating the development of science and its role in

society, thereby understanding the embedding—or alternatively, the rejection—of new medical technologies as a "socio-technical" process (Jasonoff 2004:15).

These perspectives held within the broad framework of STS that includes a range of disciplines, have also influenced the arguments made in this thesis. The study is situated at the current juncture of stem cell research elucidated here. It has been contextualised by the literature, elaborated in chapter one, that examines the range of factors—political, economic, social, medical—involved in the routine embedding of unproven medical technologies in clinical and non-clinical settings. The literature encompasses several examples, over decades, of new or experimental medical technologies—including devices, techniques and procedures—that were popularised despite contrary evidence to the technology's clinical safety or benefit. With regard to stem cell treatments in India, anthropological research of Patra and Sleeboom-Faulkner informs us of the "partly underground" local and global healthcare networks within which the provision of adult stem cell treatments were situated (Patra and Sleeboom-Faulkner 2009:160). These networks that flourished in India's highly "unequal social contexts" of healthcare access, were also helped by the easily negotiable regulatory mechanisms that worked in favour of providers (Patra and Sleeboom-Faulkner 2009:148). Other writings by Bharadwaj, and also Prasad focused on hESC provision of a single practitioner who catered largely to international medical tourists. These authors both argued that the wide scale maligning of Dr. Geeta Shroff's practice only diminished the role of her patients who made reasoned choices to experiment with stem cells. Standard regulatory measures, these authors believed, would not provide the answers or an analytical frame to the existence of unproven stem cell practices in India (Bharadwaj 2014; Prasad 2015). These studies on stem cell practices in the country set the landscape for further research on a subject that is still evolving, and is also a relatively recent area of social science interest in the specific context of India. Was it possible to further investigate the networks of provision and information on stem cell treatments that Patra and Sleeboom-Faulkner discovered? What was the nature and extent of the engagement of major stakeholders with stem cell treatments? What were the conditions or contexts of stem cell operations? These were some of the questions that the study initially set out to examine.

An exploratory study design was considered appropriate for research in a relatively unknown area. The respondents of the study were patients and/or caregivers, providers, scientists and policy makers. Purposive and snowball sampling methods

were used to identify respondents and the semi-structured interview was the main tool for gathering data. In all categories of respondents, except policy makers, only those associated with experimental or unproven stem cell treatments, regulated or unregulated, were included in the study, with the term treatment throughout the thesis, thus, implying the use of stem cells for non-established indications. Primary data from 33 patients and/or caregivers and 13 providers indicated that stem cell experimentation of largely adult stem cells was embedded in the country's mainstream health system comprising a heterogeneous mix of private and public sector institutions, varying in size, type, capacity, and also ownership with regard to private establishments. The providers interviewed, that included a patient organisation, were located in seven cities across six states and Delhi. Although all of them were in the private sector, the nature of provision had varied. Patients were charged for treatments, offered free treatment in research studies or in one-off institutionally approved cases and also in some instances, provided reduced rates than the market. The majority of patients and/or caregivers interviewed had paid for treatments in the private sector, with a few having received free treatment in research studies conducted across sectors. They had heard about stem cell treatments through health care professionals, the media, and other patients as well as from different kinds of personal associations. They sought cures for neurodevelopmental and neurodegenerative conditions such as autism, cerebral palsy (CP), muscular dystrophy (MD), spinal cord injury and multiple sclerosis (MS). In some instances, unregulated stem cell provision was situated in covert networks of legitimate practices within the private sector and in one instance it also cut across public and private sectors. There were other off-the-radar networks that also involved relatively newer and legitimate enterprises such as cord blood banks and biotechnology firms. In the varied, networked spaces of provision and information, that were situated within an overall framework of established healthcare and mainstream business practices, the formation of fixed categories between the regulated and unethical, the private and public was not always possible. Unregulated or paid-for provision was also disguised within the language of clinical trials, studies and standard ethical and scientific protocols. The clinical trial has also been implicated in the argument of normalisation of stem cell experimentation. While this study does not deny the significance of scientific standards in conducting research, it argues that the credibility of the clinical trial operation is itself under threat in India and regulations have only served to facilitate unproven stem cell practices. Moreover, patients or caregivers made no distinctions between clinical trials and unethical treatments. They made decisions about the treatment on the basis of what

they encountered or were offered in their search for cures, among which was the offer of a stem cell study. According to anthropologist Koenig, a clinical trial could in fact facilitate rather than prevent the routinisation of a new or experimental medical technology. The writings of Koenig and others who argued for a more nuanced understanding of the effects, or futility of regulation as the primary solution to controlling the use of experimental medical technologies are discussed in the literature review that explores the multiple ways in which several medical technologies considered problematic for various reasons were diffused into medical practice and became common knowledge among the lay public.

The provision of experimental stem cell treatments, like IVF and other precursors, had not been straightforward and neither was the response to it. The pathways of its normalisation were, thus, complex and constituted a dynamic engagement between science, medicine, politics and culture (Jasonoff 2004). The data made clear that an entire enterprise — of clinicians, hospitals, laboratories, agents, the media and ordinary people, were drivers of normalisation of stem cell experimentation. From the patterns that emerged in the data analysis, within and among categories of respondents, it was evident that normalisation was taking place through both micro and macro pathways that were interlinked, the latter influencing the former in various ways. Chapter two focuses on the narratives of providers, patients and caregivers in order to reveal how micro engagements with stem cell experimentation contributed to the normalisation process. As stem cell treatments were incorporated into the ordinariness of the clinic and routine life, the narratives reveal how the uniqueness of these biological entities was simultaneously retained. The stem cell was a symbol of what was new and hopeful, and as easy an option the treatment appeared to be, it was also extraordinary in what it appeared to offer (Franklin 2013). Chapter three attempts to show how structural conditions have informed and shaped the choices of patients, families and providers with regard to stem cell treatments, and to a certain extent, the scientist. The scientist who was further removed from the normalisation process had, nevertheless, provided an important vantage point from which to view the routine embedding of unproven treatments. The chapter also includes the voices of policy makers and additionally, analyses how the media in advertising stem cell technologies, promoted policy-led commodification of healthcare and created the conditions for normalisation of stem cell experimentation. Chapter four explores the emergence of the middle class experimental subject in the process of normalisation of stem cell treatments. The respondents of the study belonged to the broad category of India's—largely urban-based—middle class population. They were not India's poor

that usually constitute the experimental subject population and neither were they international medical tourists, that, so far, have been the focus of academic scholarship and media attention in the context of unproven stem cell treatments in India. Middle class patients and/or families were targets for stem cell treatments as they were for any other new medical technology in India's highly commercialised health system. Except, stem cell treatments were experimental medical technologies, commonly and easily found in frameworks of hope, access and desire rather than the current realities of intractable and incurable conditions. The commercialisation and normalisation of unproven stem cell treatments can be argued as the ultimate state of healthcare commodification (Kent *et al* 2006). How should we understand the inclusion of individuals with resources, albeit varied, as subjects of medical experimentation? Can the normalisation of stem cell experimentation be viewed as another form of biomedical control? Or should medical experimentation be included in the discourse on biomedical choice? The closing chapter of this thesis discusses the possible implications of these developments — for science, state and the individual.

Chapter one

Conceptualising Normalisation of Experimental Medical Technologies: a Review of Literature and the Study's Research Methods

I. A Review Of Literature

> Even the most awe-inspiring artefact is just that: a thing made by human beings driven or inspired by certain goals, desires, or aspirations. (Blume 1992:2)

The practice of experimental stem cell treatments in India, this thesis argues, was normalised in clinical settings and in everyday life in various ways. These ways in which stem cells in all their extraordinariness were also being made to appear ordinary, were not always clear and simple. The study finds that the practice was embedded in intricate networks of people, institutions and activities, conditioned by regulations and policies, encouraged by clinical procedures and the language of promise, and also shaped by private feelings, individual hope and personal ambition.

The routine use of experimental medical technologies is not new in the history of medical innovation and neither is the phenomenon of clinicians taking risks with patients. This chapter discusses numerous studies on medical innovation from the 19th century until the present, in order to situate the study's findings in their relevant theoretical and empirical context and provide an intellectual framework to the arguments made throughout the thesis. In the pages that follow we will see that a substantial literature from the social sciences has explored the various ways in which experimental medical technologies were accepted into clinical, social and institutional environments despite scientific research doubting the technology's readiness for patient use. The development trajectories of these medical technologies were varied. Some were short-lived and others such as in vitro fertilisation (IVF) and the ultrasound became standard practice and highly popular among the lay public, but have remained controversial. In discussing the observations and analyses of these various medical technologies, this chapter makes four main arguments: firstly, the nature of routinisation of experimental medical technologies is multi-faceted, involving various actors and interests, secondly, the progression from scientific research into clinical practice, that is the expected direction of innovation is not

always straightforward, thirdly, rules and regulations of scientific research are participants of normalisation rather than deterrents and fourthly, examples from literature discussed here, make the overarching argument that technologies are not a "self-acting force" determining human actions (Williams 1990:6 cited in Franklin 2013:4), rather they "embody the circumstances" of their constitution" (Blume 1992:46). In these statements by social scientists, Williams and Blume, was a critique of the widely prevalent theory of technological determinism that ascribes technology with an "autonomous", irresistible and invincible power to cause "social change" (Chakravarthy 2014:4). In challenging the technological deterministic approach, was not to discredit technologies that have revolutionised medicine in the past or to deny their potential of doing so again in the future. According to Blume, the 1950s and 1960s were the "'golden age'" of medical progress: an era of high expectations, widespread faith, and life-saving innovations" (Blume 2013:726). By the 1970s, however, the scenario changed the world over. An increasingly technologised medicine was contributing to rising healthcare costs and there was growing evidence of the irrational use of medical technologies in clinical practice (Blume 2013). At this juncture in countries like the U.S., clinical trials had been institutionalised into law and the idea of an ethics review of scientific research was gaining ground. In the aftermath of the disastrous effects of the drug Thalidomide that resulted in several thousand children being born with severe deformities, major legal stipulations were introduced in the U.S. for medical research on human subjects. From 1962, the pharmaceutical industry for the first time was required to prove not only the safety of the drug but also its effectiveness before marketing a product. This new rule had institutionalised the randomised control trial (RCT)[1], considered today as the gold standard of clinical research (Petryna 2009). From the 1960s and 1970s reports of unethical experiments on vulnerable populations such as prisoners and racial minorities had also come to light (Beecher 1966; Baader *et al* 2005). The sheen on new technologies was, in other words, fading and being replaced instead with distrust and public disillusionment in medicine's potential. In 1971, according to Illich, approximately 12,000 to 15,000 medical malpractice suits

[1]In a RCT, a group of research subjects is given the treatment or drug under investigation and another group is given another treatment or drug or not given any treatment at all, also known as placebo. The trial is therefore described as a controlled trial. The term 'randomized' implies that research subjects are ascribed to different groups by chance. This method is used to reduce bias among investigators who can otherwise assign the intervention to research subjects most likely to produce the most favourable outcomes. The RCT can also be a double-blinded, controlled trial where neither the investigator nor the research subject is aware of who is in the control or treatment arm of the trial (Levine 1988).

were filed in U.S. courts (Illich 1976). In the same year there were reports of deaths and serious side effects from the Dalkon Shield, an intra uterine device (IUD) widely used in the U.S. at the time. The findings from a study conducted in 1973 by the U.S. Center for Disease Control and Prevention, revealing the various risks associated with the contraceptive device, had little impact on its manufacturer who eventually was forced to declare bankruptcy in the 1980s, with more than 300,000 lawsuits filed against the firm (Horwitz 2018). At this point in the history of medicine, sociologists had begun to investigate the problems of "medicalization of society" — of defining a non-medical event, a personal crisis or all of "life's problems" including death, loss, and anxiety, entirely in medical terms (Conrad 2007:3-5). Social scientists including feminist writers expressed concern about the excessive medicalisation of specifically women's health in areas of reproduction, infertility and birth control (Conrad 2007). This was not to say that medical interventions or treatments were not necessary, Illich argued, rather the expansion of medicine into areas where "clinical care is incidental to the curing of disease" or a condition, resulted in the spreading of medicine's harmful affects among "populations" (Illich 1976:5).). Voices questioning the introduction of new medical technologies in the absence of adequate assessments of use and purpose emerged from academia and social activism, in India and elsewhere. By the 1980s and 1990s academics and women advocacy groups in India, questioned, for example, government policy on contraceptive technologies such as Depo-Provera, an injectable contraceptive, declared unsafe in the U.S. but marketed by the country's drug firms to the developing world for "mass consumption" (Dowie, Ehrenreich and Minkin 1979, para.3; Rao 2004, Sathyamala 2000; Datta and Misra 2000). In countries like Britain, Europe and the U.S., the question of how to approach the issue of controversial medical technologies also manifested in the form of new theoretical and cross disciplinary perspectives such as Science and Technology Studies (STS). Among the key arguments that constitute the common thread in the several strands of STS, was investigating how science is "always socially shaped" (Webster 2002:447). According to Webster, "technologies do not simply arrive in the health market – this has to be created, and clinicians and patients, regulatory agencies and health authorities all have to see them as of value" (Webster 2002:451). The "mobilization and stabilization of social and material networks" were, therefore, considered essential for the "successful" normalisation of technologies (Webster 2002:447). Sociologist Blume who wrote within the STS tradition, tracked the "diffusion processes" of diagnostic technologies showing how "the reaction to new medical technologies is anything but rational and measured" (Blume 1992:5). The x-ray's and computed tomography (CT) scanner's rise to fame

were outcomes of several factors, Blume argued, that included institutional and professional goals and common economic interests of both medicine and industry (Blume 1992). Anthropologists Thompson and Franklin also used an STS approach in their analysis of IVF and its normalisation. Others like Koenig and Valenstein also revealed a range of factors, social, political, economic, that ascribed "utility" and "value" to the medical treatment, indicating that scientific facts were not enough to explain the processes by which medical innovations became routinely used (Webster 2002:447). Jasonoff, on the other hand, looked at macro level factors that affected and triggered the normalisation processes involved with new medical technologies in advanced economies.

This review combines literature from the West and India with the purpose of presenting various case studies on how an experimental medical technology becomes normalised despite doubts on its safety, efficacy and benefit. It draws from certain elements of scholarship within the STS theoretical framework to argue that the normalisation of stem cell treatments needs careful analysis of every-day processes involving a range of actors and social networks as well as larger structures that dictate micro and meso engagements with new technologies. Throughout the thesis it will be clear, however, that my argument unlike STS scholars, does not seek to challenge the nature of stem cell science itself or claim, like social constructivists Pinch and Bijker, that science is one among many "knowledge cultures" (Pinch and Bijker 1987:19). Rather, it borrows from the social constructivist proposition that "explanations" for the "acceptance" or "rejection" of scientific knowledge can be found in the "social world rather than in the natural world" (Pinch and Bijker 1987:18). This argument is important in reminding us that science must not be examined as an impenetrable structure, unaccountable to the public. The writings from STS and its multidisciplinary approaches in studying medical innovation and its relationship with society have contexualised and influenced the approach of my study and its research methods, described here following the review. The literature on the normalisation and routinisation of various experimental medical technologies is discussed in the first half of the chapter. The detailed ethnographies of Thompson, Franklin and Koenig are significant for this study. Their scholarship provides the essential definition and conceptual understanding of normalisation or routinisation in the context of an experimental medical technology—revealing an ordinariness and simultaneous complexity to what normalisation means and what it does. The second half of the chapter reviews relatively recent literature on stem cell technologies in India and the West. The observations of Rose, for instance, highlight

new elements that have emerged with 21st century techno-science in the context of advanced western economies. Contemporary technologies have given patients, living in these countries, new opportunities of hoping and taking control of their health "through acts of choice", Rose argued (Rose 2007:26). The writings of Good, Novas, Rose, Brown and others on the role of hope in healthcare in contexts of choice and the biotechnology industry, have added an important analytical framework to investigating the widespread acceptance of an unproven technology such as stem cell science.

1. Defining normalisation of new medical technologies: ethnographic studies on in vitro fertilisation and therapeutic plasma exchange

a) In Vitro Fertilisation (IVF)

In 1978 when the world's first baby was born from IVF, existing notions of the natural or predetermined in human reproductive biology were redefined and reconfigured. As the technology became widely accessible to include unmarried women, "lesbian and gay consumers" it also challenged conventional understandings of family, parenthood and kinship ties (Franklin 2013:329). Today, IVF has become "more regular and even quotidian or ordinary" (Franklin 2013:9). According to Franklin, the medical procedure is perceived as:

> …normal and natural in the same way that most technologies that become highly popular and successful are quickly taken for granted (indeed, this is how revolutionary technologies are now defined). (Franklin 2013:4)

Despite known medical risks and a success rate of less than 30 percent in women under 35, the procedure is routinely offered today in health systems of countries like the U.K. and U.S. (Human Fertilisation and Embryology Authority 2014). It is "as much a part of female dialogue as waxing and highlights", a journalist wrote about IVF in a London newspaper in 2009 (Soames 2009 cited in Franklin 2013:223). In India too, an industry in assisted reproductive technologies (ART) that includes IVF has flourished, its practices largely unregulated and unmonitored. According to ICMR estimates there were about 250 IVF clinics in the country in 2005 (Sama-Resource Group for Women and Health 2008). The Council in its efforts to monitor the industry's growth recently established a registry—although voluntary in nature—of ART clinics in India. In February 2018, the registry had 148 "confirmed ART clinics" from across the country (ICMR n.d.), a poor indicator, most likely, of the industry's

size, with the Indian Society for Assisted Reproduction having declared over 600 members in 2005 (Sarojini, Marwah and Shenoi 2011:4). Attracting international medical tourists is an important segment of the ART business. Each IVF cycle in India costs about 90,000 rupees, a fraction of the amount charged by clinics in the U.S., for example, where patients pay rupees 9,00,000. The Indian market today has also expanded its local client base with IVF clinics having spread to "semi-urban" locations in the country (Sarojini, Marwah and Shenoi 2011:4). Success rates are manipulated and "inflated" by clinics that offer discounts, packages and deals such as "egg-sharing" in order to reduce costs (Sarojini, Marwah and Shenoi 2011:6).

Both Franklin and Thompson explored the meaning of "normalization" and "naturalization" of IVF in clinical settings, in their ethnographic research in the U.K. and U.S., respectively. According to Thompson:

> Normalization includes the means by which 'new data' (new patients, new scientific knowledge, new staff members, new instruments, new administrative constraints) are incorporated into preexisting procedures and objects of the clinic. (Thompson 2005:80)

In the early stages of IVF, Thompson observed that clinics adopted various "strategies" to ensure an easy and smooth introduction of the new procedure into healthcare practice (Thompson 2005:80). Among these strategies were "filtering mechanisms" used by IVF clinics in order to select only certain kinds of patients for the treatment. These were essentially white, middle or upper class couples who already enjoyed better healthcare access in America's commercialised and privatised health system (Thompson 2005:82). The IVF clinics, by invoking dominant social norms of class, race and parenthood had attempted to embed the technology within boundaries of what was considered acceptable and mainstream, argued Thompson. Patients with the " 'right' " "attributes" of "heterosexuality", stability and " 'the ability to pay' " had been codified within the clinic and more significantly were made to appear as people who would be normally and naturally encountered in IVF clinics (Thompson 2005:81-87). "Naturalization", according to Thompson, was therefore an integral aspect of normalisation, with clinics adopting several practices to produce and reproduce a world of IVF shaped by "what is already there" (Thompson 2005:80). The normalisation strategies were, thus, not linear practices that merely involved the practical application of medical knowledge on women's bodies, Thompson explained. Rather, these techniques "enable [d] infertility to be

understood", IVF to be performed, patients to be selected and acceptable behaviour to be adopted by both staff and patients (Thompson 2005:80). Thompson's presence as a researcher in an IVF clinic was also subjected to the normalisation strategies used by clinical staff. In one of the clinics of Thompson's study, she was asked to wear a "white coat" during her fieldwork and was given the title of "visiting scientist" (Thompson 2005:82-83). These attributes had "normalized" her "presence" in the site and had "assimilated an unclassified outsider into the things that are normal in clinics—doctors and scientists in white coats", said Thompson (Thompson 2005:83). Moreover, the doctor's coat and title had also "naturalized" her presence during patient checks ups and rendered her "ethnographic gaze" as non-threatening (Thompson 2005:79-83). Thus, while a certain kind of patient presence in the clinic had been naturalised by explicit markers of what is natural or normal so had the ethnographer's.

By the late 1990s, as IVF became routine in the U.S. and providers widened their client base beyond wealthy white couples, Thompson observed that patients also went "through their own changes over time about what seems natural…and what seems frighteningly or impossibly unnatural" (Thompson 2005:141). With interview excerpts, Thompson illustrated how women cited kinship norms that were familiar and meaningful to them in order to transform the strangeness or "newness" of IVF "into the realm of the acceptable" (Thompson 2005:141). For example, an African-American patient named Paula expressed a strong preference for her sister or a friend to be the egg donor. She explained that it was not an "unusual" practice for women from her community to acquire the role of a ' "mother" ' or ' "second mother" ' for the children of friends or relatives (Thompson 2005:158). Since it was quite natural for either of these kinship affiliations to share the role of motherhood, involving them in a family built on IVF would seem "appropriate" rather than an unnatural outcome of "monstrous innovations" (Thompson 2005:141). In this example, the natural state was perceived to have been destabilised by IVF, and under such circumstances a conventional or even "hyperconventional" reality was often mobilised in order to "normalize the newness" of the technology "as much as possible" (Thompson 2005:141-142). This process of IVF's embedding within conventional notions of kinship, gender roles and parenthood was crucial to its success as it is "precisely" these identities that were "threatened…in the face of infertility or unwanted childlessness", Franklin argued (Franklin 2013:234).

Franklin complicates the discussion on IVF's normalisation. She argued that the medical technology is as "curious" as it is "ordinary" (Franklin 2013:6) because it is "rarely, if ever, just" about a baby (Franklin 2013:232), or "simply a response to a desire to have children" (Franklin 2013:18). Franklin draws from feminist literature on the subject as well as her own findings to highlight the "obvious" and as well as the hidden struggles of women who have undergone IVF (Franklin 2013:6). For example, she cited feminist scholar and activist, Christine Crowe, who argued how expectations of women undergoing IVF changed or evolved over time and as a result ended up being quite different from when they started. For many of these women, "to being seen" by families or social circles "to try to become pregnant" if not actually pregnant became reason enough for them to undergo the process, stated Crowe (Franklin 2013:213). In other words, the IVF process developed into a coping mechanism for women dealing with social pressures and gender expectations. It provided them with visible signs of attempting every option available to achieve motherhood even if they didn't succeed in the end. The procedure, while providing choice and "resolution" to the stigma of childlessness, thus, also simultaneously under the shadow of uncertainty had exacerbated feelings of inadequacy that it intended to alleviate to begin with (Franklin 2013:233). In other words, IVF takes away but also adds new and unfamiliar elements to conventional frames of family and parenthood, such as "new kinds of biological relatives, as well as new models of biological relatedness" (Franklin 2013:16). The overall result is not quite exactly a reproduction of what exists but rather a "hybrid culturing" takes place, said Thompson, as the new gets incorporated into the old (Thompson 2005:115). A state of "being nearly, or partially, pregnant" (Franklin 2013:238) was among the "new biological facts" that Franklin found women had experienced during IVF (Franklin 2013:239). Citing the work of Margarete Sandelowski, Franklin explained that this state of feeling pregnant but not actually being pregnant is because IVF treatment comprises "carefully managed, highly monitored" stages such as embryo "implantation" that are being mapped for each success or failure, deciding how close or far the body is in achieving its final goal (Franklin 2013:238-239). The process of treatment itself rather than the outcome becomes significant for women that hold on to familiar emotions of hope but also develop innovative ways to embrace new or unanticipated terrain. Patients begin to perceive the experience through the "phases" they undergo allowing for "the novel sensation" of being "partially pregnant" that would not occur in situations of "unassisted" pregnancy (Franklin 2013:238). The thrust of Franklin's argument, therefore, lay in demonstrating how the "normalizing systems that" IVF "both relies upon for its success and reproduces through its

workings" (Franklin 2013:7) also reveals "what is not obvious about its workings at all" (Franklin 2013:6). Feelings of "ambivalence" about IVF, were thus, an inextricable part of normalisation of new technologies, Franklin emphasised (Franklin 2013:7).

The "paradoxical patterns" present in society's engagement with IVF were, however, "hardly unique" to it (Franklin 2013:235). The reproductive technology made its public appearance when the "era of unquestioning enthusiasm for medical" progress that existed right until the 1960s was being challenged by several groups including patients, social scientists, feminists, policy makers and also the medical profession (Blume 2013:726). The scholarship emerging from the broad disciplinary realm of STS attempted to develop a " 'science of science' " (Edge1995:7), previously "assumed to be pristine and beyond the realm of social analysis" (Lock 1988:3). The observations of Franklin and Thompson revealed how the normalisation process was not an indication of modern science imposing itself "on preexisting social categories", but rather an interaction of the technical and the social had determined how IVF was defined while it was also familiarised (Thompson 2005:115). Asking similar questions to Thompson and Franklin, but taking for granted the "technological imperative in medical practice", was medical anthropologist Koenig who emphasised the role of social factors in the "routinization" of another type of experimental medical technology known as Therapeutic Plasma Exchange (Koenig 1988:466). The new medical technology was introduced into hospitals across the U.S. and the U.K., in the 1980s, despite its high costs and insufficient scientific evidence on its effectiveness in treating autoimmune disorders. The following sub section discusses Koenig's contribution to the importance of social analysis and ethnographic observation in examining how routinisation occurred in medical settings (Koenig 1988).

b) Therapeutic Plasma Exchange (TPE)

Koenig in her ethnographic observations of TPE's routinisation assumed society's "basic cultural infatuation with technology" (Koenig 1988:466). Her interest instead lay in examining "social processes, which contribute to the operation of a technological imperative in medical practice" (Koenig 1988:466). Experimental technologies introduced an "omnipresent uncertainty" to "clinical encounters", stated Koenig who observed how clinical staff, including doctors, performed repetitive, non-clinical tasks in the TPE unit in order to dissipate the tension prevalent on account of the possible risks in using the new TPE machine (Koenig 1988:479). Koenig described these tasks as "ward" or "treatment rituals" that included nurses giving tea and biscuits to patients at the end of every procedure or a physician hurling a "waste

bag" of "saline" "into the sink" every time the intricate procedure of connecting the machine to the patient was successfully done (Koenig 1988:479-481). In maintaining a sense of normalcy in otherwise uncertain contexts of experimental medical technologies, these rituals performed similar functions to the normalising strategies adopted by IVF clinics and women seeking IVF treatment. Rituals "disguise the reality…that the patient's condition might not be treatable with any known method, and that the therapy is only a chance which may or may not work", explained Koenig (Koenig 1988:482).

The "mysterious" aura that initially surrounds a new medical innovation eventually loses its extraordinariness as its use increases, Koenig observed (Koenig 1988:486). With increasing routinisation of TPE, the chaos and uncertainty in using an unfamiliar, experimental technology was replaced by a sense of order in the clinical setting. Koenig described the "social scene" in the hospital when the new TPE device had been introduced as very disorderly with "IV poles falling to the ground and physicians running in and out of the room" (Koenig 1988:474). In contrast, the older TPE treatment was indistinguishable from the daily humdrum of the hospital. A nurse "sitting calmly" by the TPE machine with "half of her attention" on the morning paper or a patient describing TPE treatment as normal "as swallowing an aspirin for a headache", compared to her "previously" thinking it " 'an oddity' " — were compelling signs of routinisation, described by Koenig (Koenig 1988:474). Routinisation, was thus, understood by her as a social process that culminated in a "state of ' "ordinariness" ' and orderliness (Koenig 1988:469). It was an important means of achieving normalisation, Thompson also stated (Thompson 2005).

The association of normalisation or routinisation with social order suggested a Foucauldian influence in the conceptualisation of the normal. According to Foucault, normalisation was a disciplining tool and therefore inevitably connected to relationships of power and authority. To normalise, he stated, was to create order in social organisation and to bring the marginalised, deviating subject—in this case an experimental medical technology—within the purview of the mainstream (Shapiro and Schwan 2011). The experimental or unfamiliar TPE initially had a disrupting influence on the hospital's usual routine and social structure. As the experimental procedure became regular practice, nurses and physicians who previously worked together on almost equal terms in order to unravel the mechanics of the new technology, had retuned to their former roles and existing social hierarchies. For the physicians, the technology's incorporation into everyday hospital systems meant that

they could transition to the next step of using TPE for deriving clinical data (Koenig 1988). For the nurses, the "ward rituals" they practiced were useful in creating an environment of "calm" in the likelihood of problems arising for patients treated with TPE even after its routinisation. In other words, business at the hospital returned to usual after the new TPE procedure became familiar but there were still uncertainties about its use. Conducting " 'scientific' " assessments of TPE had been hard at best due to many unknown factors of the diseases that TPE treated (Koenig 1988:472). The change that occurred in the technology's "status" from an experimental technique to "standard of care" in the hospital, despite the ambiguities, was thus an outcome of the "social setting itself" (Koenig 1988:466). The essence of Koenig's argument lay in the fact that meanings ascribed to TPE were found within the "social and cultural forces at work in the technological imperative" (Koenig 1988:472).

According to clinicians Fineberg and Hiatt, "many forces other than results of objective evaluations affect the rate and extent to which a medical technology spreads in practice or is abandoned" (Fineberg and Hiatt 1979:1089). "These include:

> …the severity and urgency of the problem addressed by the technology, the availability and suitability of alternative approaches, financial and other advantages to the physician or hospital, compatibility of the new technology with the current style of practice, the prestige and visibility of its advocates, the channels through which the physician…learns about it, the process by which decisions are made to adopt the technology, promotional efforts of manufacturers, applicable laws and regulations, patient preferences and the physician's general attitude toward innovation. (Fineberg and Hiatt 1979:1089)

In the following pages, other examples of experimental medical technologies are discussed to further emphasise the various compelling factors in technological usage that Fineberg and Hiatt alluded to, and which are involved in the normalisation of "innovative or controversial" medical technologies (Fineberg and Hiatt 1979:1086).

2. Rise in popularity of experimental medical technologies: the role of medical professionals

In 1979, the same year that Fineberg and Hiatt wrote about the urgency of evaluating medical innovation, the U.S. National Academy of Sciences published a report on the diffusion practices of machines, systems and services as well as innovative surgical procedures and drugs in the country's health system (National Research Council and Institute of Medicine 1979). It seemed obvious, the report stated, that the more

efficient and effective medical technologies would be prioritised in hospitals, but this was not always the case. At the time of the publication, there was full awareness in scientific and policy circles that experimental medical technologies such as foetal monitoring and the CT scan had been widely diffused into medical practice without sufficient evidence on safety and or benefit. The Academy concerned with the issue of experimental technologies being adopted so readily in medical practice commissioned its own case studies on various experimental medical technologies such as gastric freezing. Concerns at this time emerged from within science and medicine and as well as from the new sociology of technology, an integral component of the STS framework. These diverse interest groups shared the common objective of investigating the range of external forces—economic, historical, organisational, political and ideological—involved in technological diffusion. This section and the next, reveal through several examples of studies undertaken, that the dynamics of normalisation are multidimensional, non-linear and fickle in nature, involving concerns and interests of doctors and institutions and larger forces of state and industry.

a) Gastric freezing

The procedure of gastric freezing for ulcer disease, although short lived, became regular practice soon after its inventor Dr. Wagensteen published his "dramatic" findings in a prestigious science journal in 1962 (Fineberg 1979:176). Wagensteen, an eminent professor of surgery in an American University, described the new treatment as a "simple, safe and effective" alternative to surgery that was ready to "become accepted practice" (Fineberg 1979:176). The Professor's discovery, that was "a sensation among the public…the medical profession" and the media, was refuted not long after his initial announcement (Fineberg 1979:176). The treatment's safety and efficacy was doubted by some clinicians and as early as 1964 published medical material had declared gastric freezing "not worthwhile" (Fineberg 1979:180). This critique notwithstanding, positive reports on the procedure persisted that year and continued until 1966, when finally it "had spent its course" (Fineberg 1979:182).

In explaining what might have caused this "early" and "rapid" spread of gastric freezing, the Academy's study showed the relationship between evaluation of a technology and its diffusion to be not quite so straightforward as expected (Fineberg 1979:186). Gastric freezing could not be easily dismissed as a "crackpot scheme produced on the fringe of medicine" (Fineberg 1979:186). On the contrary, the senior surgeon had received funding from the U.S. National Institutes of Health and

followed scientific protocols by experimenting on human subjects only after animal testing had proven to be successful. According to the report: “a respected surgeon advocating a nonsurgical treatment may be especially credible, and the allure of nonsurgical treatment appealed to well-informed physicians as well as to the public” (Fineberg 1979:186). The study also found that “information from colleagues”, rather than publications, could be the determining factor in how clinicians interpreted “new findings” or the latest research (Fineberg 1979:188). The report described other reasons for gastric freezing’s popularity in addition to the procedure’s simplicity, the innovators “stature” and peer influence (Fineberg 1979:186). These included the “significant prevalence” of the disease, the high risks of surgery, the potential for profit for the medical profession, the role of popular newspapers and television, and to say the least, desperate patients looking for cures (Fineberg 1979:186). Concerns raised in some quarters about the need for more rigorous clinical data on the procedure and the difficulties in conducting well designed multi-centre trials were, therefore, “only part of the problem” the report concluded, as the study had revealed other compelling influences in the procedure’s fast rise to fame (Fineberg 1979:188).

A closer look at the role of physicians in promoting experimental medical procedures is found in Valenstein’s seminal work on the “radical” brain procedure of prefrontal lobotomy (Valenstein1986:22). The following section gives a brief overview of Valenstein’s account, that unlike other studies discussed here, foregrounded the personalities and agendas of individual physicians whose influence was an essential factor in the three decade long practice of a highly experimental procedure involving: “drilling two or more holes in a patient’s skull”, inserting “various instruments” inside it and destroying parts of the human brain, “often without” the surgeon “being able to see what he was cutting” (Valenstein 1986:3).

b) Prefrontal lobotomy

The invasive surgery involved in prefrontal lobotomy was considered treatment for the mentally ill in mainstream psychiatry, from the 1930s until the 1970s, in the U.S. and Europe. Eminent surgeons, highly respected for their contributions to medicine, performed and promoted the surgery. The “energy and determination” they had for the medical profession only drove them further in their ambition to popularise a drastic intervention, as a legacy to “themselves” and to the history of neurological medicine (Valenstein 1986:5). Among them was neurologist Egas Moniz, who believed he could perform brain surgery on humans “with impunity” and dismissed the necessity of animal testing that usually precedes human experimentation

(Valenstein 1986:102). The physician's justification for the surgery had been very "vague" and devoid of any theory, described Valenstein. However, due to constant repetition of his conviction in the procedure, Moniz's practice had "acquired a veneer of truth and was accepted (or at least repeated) by many other people" (Valenstein 1986:99). In winning over his critics, Moniz was also helped by fellow clinicians who paid "little attention to the validity of the claims of success" made by members of their profession (Valenstein 1986:6). Opinions were divided among mental health professionals on the causes of mental illness, stated Valenstein, and this uncertainty in diagnosis gave added impetus to the popularity of the risky practice. Neurosurgeons emerged the obvious winners in the contested medical terrain as they offered a tangible option to patients "many of whom had abandoned hope" and "sought out the physician's in their desperation to find cures (Valenstein 1986:5). The mainstream news, "whose readers numbered in millions", also played its part in generating an interest in the procedure among patients and families, stated Valenstein. Every " 'miracle cure' " was reported "with uncritical enthusiasm", without any attention paid to the risks and failures of the surgery (Valenstein 1986:5).

In this "therapeutic and theoretical vacuum" prefrontal lobotomy was also encouraged or at least not challenged by state run, mental asylums in the U.S. (Valenstein 1986:34). Unable to withstand the economic burden of housing large numbers of the mentally ill, the availability of a medical solution for these institutions was a relatively inexpensive way of reducing their patient load. Although the majority of operations were performed in public hospitals, a "substantial number" were done in private institutions or hospitals for wealthier and "socially advantaged patients" (Valenstein 1986:4).

The factors that contributed to the rise of prefrontal lobotomy were therefore many, argued Valenstein. He summarised them as: "opposing theories of mental dysfunction", "political struggle…between psychiatrics and neurologists", "desperate human need", the offer of a cure, "the "popular press", "uncritical acceptance by the medical profession" and "determined and ambitious" doctors (Valenstein 1986:6). The popularity of the surgical procedure receded only in the 1970s when alternative therapies appeared in the form of drugs and psychoanalysis. In this time period, social scientists including "psychologists, and psychiatrics" argued against medical interventions for mental disorders whose causes, they contended, were rooted in "family and society" (Valenstein 1986:288). Mentioned in the introductory pages of this chapter, grass roots movements of the 1970s in the U.S. and protests against

problematic medical practices did effect change in state policy, although questionable and in varying degrees. For instance, the U.S. National Commission for the Protection of Subjects for Biomedical Research, established in 1974, was disapproving of prefrontal lobotomy being performed for " 'social or institutional control' ", leaving it to institutional review boards to permit or deny surgery after an ethical evaluation (Valenstein 1986:288). The Commission, rather than prohibiting psychosurgical interventions entirely, introduced a level of oversight for surgeons. In doing so it reached "for a compromise" between science and public interest "but fell only slightly short of endorsing these operations", argued Valenstein (Valenstein 1986:289).

Valensetin's account is significant in drawing attention to events in medicine that demanded a more thorough investigation of the forces at play in the sustanined rise or fall of new medical interventions. The literature discussed here has argued for a complex reading of medical innovation, involving a range of issues and actors, with some assuming lesser or greater importance depending on the technology and the circumstances of its development and acceptance. Individual physicians were on the forefront of technological change in the examples discussed in this part of the chapter. In the following section we will see how industry and medical institutions were also major players in promoting medical technologies when evidence of clinical use and benefit was inadequate, and in some cases, where possible medical risks were also known. The role of the medicine-industry nexus was most obvious in the diffusion of diagnostic technologies, argued Blume, who tracked the controversial but flourishing "careers" of imaging technologies like the x-ray and the CT scan (Blume 1992:68).

3. Diagnostic technologies: extending the discussion beyond the clinic

In 1895, the x-ray "took the world by storm" and "a "thriving and dynamic x-ray industry" developed "with remarkable speed", observed Blume (Blume 1992:21-23). The x-ray's inventor, Roentgen, not having patented his discovery, resulted in a free-for-all environment for the industry. As early as 1896, the General Electric Company was the first to capitalise on the x-ray's market potential with several British and U.S. firms following suit. Growing reports in 1900 of x-ray operators suffering burns did not diminish the technology's interest in hospitals that had begun to purchase x-ray equipment soon after it was commercially available. Not every clinician was however convinced of the x-ray's diagnostic capabilities and for radiologists who operated these machines, rising up the professional ranks had been an uphill task. The x-ray,

although nothing short of a miracle, was so simple to operate that in its initial stages "anyone with access to a physics laboratory could try it out", stated Blume (Blume 1992:22). Even non-physicians acquired the machine without necessarily having the specialised knowledge to use it, thus, making it harder for radiologists to be taken seriously (Blume 1992). It was only by the 1930s that radiology was establishing itself as a medical field in its own right. World War I was crucial in proving the clinical value of the x-ray and for the industry too, both the world wars had been highly profitable for business[2] (Blume 1992). Public expectations of healthcare had also changed with WWI, when medical services were introduced in more structured ways for the first time. Medicine at this historical juncture became a more precise science and clinical research developed as a discipline that relied on technological tools for "reproducible observations", a hallmark of the scientific method (Blume 1992:14). At the same time, an insurance industry required clinicians to examine patients in more precise ways, demanding a greater dependency on technology. It is was within this context of social and historical processes that a "powerful coalition of the leaders of medicine" and "industrial capitalism" had emerged, with an interdependence that was mutually reinforced, argued Blume (Blume 1992:20).

By the 1970s, the x-ray was routinely used in "modern hospitals", seemingly undeterred by growing evidence in the 1960s of the cancerous risks it posed for the foetus (Blume 1992:28). In analysing why the technology was purchased by institutions regardless of negative reports on safety, it was clear, according to Blume, "that significantly more than profit is involved" (Blume 1992:9). Greer, cited by Blume, argued that this phenomenon of technological diffusion could not be explained by generalising the power of the medical profession. There were specific interests involved such as those of radiologists and pathologists who encouraged the adoption of new technologies. In subsequent decades, x-ray usage had extended to highly specialised medical fields propelling the industry to keep abreast with medical advancements. A "growing interdependence" between radiologists and manufacturers developed, and "the perspectives on innovation of an increasingly oligopolistic industry and an increasingly professionalised radiology were becoming more and more attuned to one another", said Blume (Blume 1992:35). Referring to the scholarship of Granovetter, Burns, Law and Callon and others, Blume argued that economic activity within the medical-industry complex was also linked to social

[2] Technological expertise developed during the war years needed avenues for reinvestment in the post war period and medicine had proven to be a lucrative market (Blume 1992).

connections and networks between “buyers and sellers” who “often become “friends” (Blume 1992:57).

According to Greer, in the case of large-scale technologies such as the CT scan, hospital management issues including “ ‘market share’ ”, “staffing policies” and the hospital’s “ ‘image’ ”, were also major considerations in acquiring technologies (Greer cited in Blume 1992:10). Institutional priorities thus featured as prominently as the needs of clinicians and organisational dynamics, according to Blume, assumed a kind of “copying behavior” with hospitals purchasing new technologies in order to compete with other institutions rather than any rational, need based assessment (Blume 1992:11). Blume referred to DiMaggio and Powell who introduced the concept of “ ‘institutional isomorphism’ ” to explain how the goal of “improving performance” for instance, which could be the initial objective of adopting a medical technology was “gradually” replaced by a desire for “status” and “distinction”, for both hospitals and physicians (Blume 1992:11). The CT scanner, for example, was “promoted aggressively by influential hospital-based physicians” despite high costs and doubts regarding its clinical benefit (Banta 1984:84 cited in Blume 1992:183). Any “self-respecting department of radiology simply “ ‘had’ ” to have” the machine Blume pointed out (Blume 1992:188-189). Soon after the CT scanner was marketed in 1973 by the British firm EMI or Electric & Musical Industries, the technology was purchased by U.S. hospitals located in practically every state of the country (Banta 1980). The U.S. was an important market for EMI. The country had greater resources for product development and its healthcare market was already highly commercialised. According to Banta, by 1975, only two years after the first scanner was set up, 100 machines were being placed in hospitals in the U.S. at the rate of 20 scanners a month (Banta 1980). The eagerness with which physicians and hospitals promoted the technology, belied the lack of basic knowledge on using “CT scanners…medically”, argued Banta (Banta 1980:266). According to Creditor and Garrett, in 1975 when 100 CT units had been ordered, none of the English clinical publications that year provided adequate data on the safety and benefits of the scanner (Creditor and Garret 1977). Radiologists were not willing to wait for scientific data on the CT scanner as using the machine was in itself a way to procure results on its effectiveness (Blume 1992). In 1974, only a year after the CT scan was marketed, Gawler and others wrote in *The Lancet* that it “would be tragic for such a promising diagnostic method” if inexperienced practitioners were to become the reason for erroneous readings of the scans (Gawler *et al* 1974:419 cited in Blume 1992:180). The authors also warned that, similar to the x-ray, the ease in operating

the CT scanner could encourage its irrational use by clinicians (Gawler *et al* 1974 cited in Blume 1992). The medical profession had, thus, expressed concerns on the injudicious use of the machine almost simultaneously as its appearance on the market, but their call for a more discerning practice of CT scanning obviously went unheeded. “It is not easy to explain the diffusion of CT scanners”, stated Banta (Banta 1980:264). The technology’s “extraordinarily rapid” spread came “to exemplify the problem of “ ‘technology run wild’ ”, untamable even by state regulations (Banta 1980:251). Discussed in more detail later, Banta argued on the ineffectiveness of health policies and “planning agencies” in the U.S., in controlling the widespread use of expensive technologies that were proving to be inconsistent with medical care and public health needs (Banta 1980:267).

Another case in point that illustrates the little impact that state regulations have had on the indiscriminate and unethical use of a diagnostic technology is the practice of the ultrasound in India. Despite the country’s Pre Natal Diagnostic Techniques Act of 1994 that prohibited the technology’s application for sex selective abortions, its use has persisted in “underground” operations with “local doctors” and “radiologists” as well as “nurses and auxiliary nurse midwives…benefitting monetarily” from the practice (John *et al* 2009:17-18). As far as users are concerned, technologies are inevitably more accessible to those with greater purchasing power but the poor are also targets in India’s highly commercialised health sector. John and others argued that social mobility among lower income groups and greater flexibility in access to resources has widened the ambit of access to the ultrasound. The authors cited a case of an “upper caste/class employer” who “loaned” money to a “lower-caste/class employee” for an ultrasound examination, thus, complicating social categorisation and differentiation in access to medical technologies in the country (John *et al* 2009:18).

Today, India “has more ultrasound machines per population than the west” (John *et al* 2009:18). As in other parts of the world, the technology’s use has been routinised—to at least three tests—for every normal pregnancy. According to Rao’s approximate estimate of the ultrasound market in India, based on the number of tests prescribed and 25 million births annually, there are about 38 million ultrasounds performed every year (Rao 2017). The thrilling experience of seeing ones unborn child on a screen has also created misconceptions among the public on the ultrasound’s actual purpose of examining the health of the “placenta”, “cervix and uterine wall” etc. (Eurenius *et al* 1997; Filly and Crane 2002:715). If the ultrasound

turns out " 'normal' " it is often interpreted as the foetus being ' "normal" ', explained Filly and Crane (Filly and Crane 2002:717). Many families even get to keep the images as a "memento" of a happy moment, an event "atypical of other medical procedures" (Filly and Crane 2002:713). The experience of getting an ultrasound can therefore be described as a "social" phenomenon, an "expectation" so deeply embedded "in our society" that people "do not ask their obstetricians if they need a sonogram, they ask when it will be scheduled", argued Filly and Crane (Filly and Crane 2002:713). The routinsation of the ultrasound has occurred the world over, despite scientific ambiguity on its effectiveness in preventing "perinatal morbidity or mortality" in "healthy" women (Filly and Crane 2002:713-714). In 1984 an "expert panel" appointed by the U.S. National Institutes of Health, found "no convincing evidence" of using "routine sonographic screening" in preventing "low-risk" women from harm (Filly and Crane 2002:714). It had reached this conclusion after considering all the evidence available on the technology usage.

Debates on the questionable use of the ultrasound were, thus, already prevalent abroad when India's imports of medical devices such as the CT scan and ultrasound increased substantially during the economic reforms of the 1990s (Filly and Crane 2002; Mahal, Varshney and Taman 2006). The country's new economic policies made it possible for the easy availability and use of the ultrasound that also proved advantageous to advancing existing social norms of male child preference and gender discrimination. A micro-level analysis on the "negative female-male sex-ratio in northern India" by John and others, showed that family planning had increasingly moved from "selective female neglect" to "planned household strategies" for using technologies to achieve the desired family makeup (John *et al* 2009:17). In addition to existing patriarchal structures, male child preference as the obvious reason for sex selective abortion thus became increasingly complex, involving a combination of factors. For instance, "agrarian crisis" in rural Punjab resulted in the preference for only "one son" families and meanwhile girls were found to be staying home longer than desired due to higher levels of education in wealthier regions and an overall trend in relatively later marriages (John *et al* 2009:17). These shifts have replaced "daughter undesirability" with "daughter-aversion", John and others argued (John *et al* 2009:17-18). Social change is, therefore, necessary in "caste, kinship, descent and inheritance norms" if attempts to curb misuse of new technologies are to be effective, the authors concluded (John *et al* 2009:18).

These examples that linked “technological change” with “social change” “in some essential manner” also showed the interdependence between the two (Blume 1992:53). In the case of India, Baru also commented on concurrent social transformations that gave fillip to new policies for further privatisation of healthcare during the country’s economic restructuring (Baru 2006). Agricultural wealth in some parts of the country led to the growth of a middle class even in rural areas. This population that invested in the social and economic mobility of younger generations through education could now better afford private health services that they expected would offer them new and modern medical technologies and treatments. “Typically the ‘new middle class’ found the public system inadequate to meet their needs and in those regions where there was a vibrant private sector they started moving out of the public sector”, stated Baru (Baru 2006:10). In the 1960s and 1970s, sections among this class went abroad as professionals, resulting in a “globalised middle class…who had both urban and rural roots” (Baru 2006:10). Doctor-entrepreneurs like Prathap C. Reddy returned to India during its economic liberalisation using policy shifts to their advantage. From the 1980s onwards, private investment in healthcare was incentivised at a much larger scale by new state policies providing industry with subsidies on land and concessions on the import of technology. Reddy’s successful negotiations with the Indian government led to the establishment of the Apollo group of hospitals in 1983, giving India its first corporate healthcare chain. After Apollo, other large Indian business houses including regional players followed suit. They established tertiary healthcare enterprises, attracting customers with highly specialised treatments that required new medical technologies (Baru 2000; Lefebvre 2008; Hodges 2013).

It is impossible therefore to view technological innovation as a single event, said Blume. Similar to Thompson, Franklin and Koenig, Blume also explored how the acceptance of a new technology was “contingent” upon the ease within which it assimilated into existing social structures and whether or not key actors were able to build productive relationships that ensured the technology’s smooth adoption (Blume 1992:59). In the case of the social impact of the ultrasound in India, John and others also contended that skewed child sex ratios cannot be explained by “any one process or structural feature” but rather “one must understand particular conjunctures of processes and features” (John *et al* 2009:18). Given these understandings of technological acceptance and diffusion, a “reliance on regulation”, the obvious route to monitor the use of medical technologies, cannot be the best or only answer to “the ills of our medical care system”, believed Banta (Banta 1980:267). Others like Banta

also saw regulation as an ineffective means to control the use of medical technologies (Banta 1980). According to Koenig, "it should be fairly obvious" that "once a new machine is in use, even in a limited way, it is very difficult to change course…its use becomes entrenched" (Koenig 1988:487). Koenig thus argued that the RCT would only serve to hasten the routinisation process rather than prevent it from occurring (Koenig 1988). Moreover, she observed that clinicians functioning under a moral imperative to treat sick patients "would break their own rules of scientific excellence, often providing treatment…not part of established controlled trials or in the face of contradictory evidence" (Koenig 1988:486). The assumption, therefore, that the use of unsafe or unproven medical technologies will be controlled entirely by regulation or assessments of scientific rigor is misplaced and oversimplified, Koenig argued. She cited Valenstein who was also doubtful whether scientific and ethical principles applied as blanket rules would in actual fact prevent physicians from performing controversial procedures. Although regulations are necessary, said Valenstein, he also drew attention to the many instances in medicine that demand the discretion of clinicians beyond the established protocols of science. These instances could occur when the basic mechanisms of an effective treatment are not understood or when scientific facts of a known therapy have been proven "false" at a later stage (Valenstein 1986:295). Under such circumstances of uncertainty, a clinician taking risks is not necessarily an act of "genius" stated Valenstein, but simply demonstrates a "willingness to take these risks" (Valenstein 1986:100). He presented the history of prefrontal lobotomy as a "cautionary tale" for the reasons that led to its practice "are still active today" in mainstream medicine (Valenstein 1986:4). Valenstein's account strongly emphasised that:

> …experimentation by clinicians outside established medical boundaries, is not a phenomenon that belongs to medical history but has remained a " 'part of the bone and marrow' " of clinical practice. (Valenstein 1986:291)

The literature discussed in the next section supports Valenstein's claim and validates his concerns. Factors contributing to the embedding of 21st century medical technologies such as stem cell therapies are similar to those of previous eras. Additionally, current scholarship on recent developments in experimental medical technologies has also introduced new dimensions to routinisation processes such as the role of hope in medical advancement. These additional analytical frameworks are critical to understanding how new technologies with uncertain futures,

notwithstanding, have still successfully captured the imagination of the public, policy makers, legislators, scientists and clinicians alike.

4. Stem cell experimentation in India: new subjectivities in a globalised and neoliberal disease paradigm

Stem cell experimentation in India had striking parallels to the academic accounts of experimental medical technologies discussed in previous sections. Patients explored unproven stem cell treatments in the hope of finding cures; the media manipulated their hope by promoting the promise of new medical technologies; and the general perception of stem cells as harbingers of health and healing was emboldened by enterprising doctors, an unregulated private sector and a growing biotech industry. The difference today in the literature on contemporary medical technologies lies, however, in the special attention given by social scientists to users of experimental therapies and the rise of new subjectivities that have emerged in the context of public engagement with medical research and experimental treatments. For instance, the ethnographies of Bharadwaj and Prasad on stem cell experimentation in India were based essentially on provider and patient narratives. Both authors raised issues similar to Rose, Miller and Novas, who write on the development and impact of biotechnology in advanced western economies. While situated in different structural contexts, these authors share in common their advocacy of the personally transformative capabilities of new and experimental medical biotechnologies. They have argued that the various pathways by which individuals find experimental treatments and engage with new knowledge has empowered them to decide the future course of their disease. The role of subjective experiences must, therefore, be made central to our understanding of technological change, these authors stated (Novas 2006, Miller and Rose 2008; Bharadwaj 2014; Prasad 2015).

Bharadwaj and Prasad confined their independent studies of stem cell treatment in India to a single provider, the infamous Geeta Shroff. A private practitioner in New Delhi, Shroff currently runs a successful business providing unproven stem cell therapies for a range of conditions. Since 2002, when Shroff started her stem cell practice at her clinic NuTech Mediworld, she claims to have used hESC cells to treat over 1,000 patients from: “India to Iraq, from the USA to the UK, from Australia to Argentina” (NuTech Mediworld n.d. cited in Prasad 2015:138). Described as “maverick, unethical, and “dangerous” by the local and international media and condemned by the scientific community at home and worldwide, Shroff continued her practice undeterred (Bharadwaj and Glasner 2009:84). The “proof” of her work lies in

her patients, she argued in the international media (Sky News 2006 cited in Bharadwaj and Glasner 2009:90). Drew Griffin, the narrator of a CNN documentary made on Shroff, titled, " 'Selling a Miracle' ", stated that he "truly" believed that the clinician "believes that she is doing right by her patients…"(Koleva 2012). Shroff's challenge to scientific authority and public scrutiny exemplified Valenstein's analysis of the nature of clinicians whom he believed to be truly "convinced of the validity" of their findings despite dubious outcomes (Valenstein 1986:294). According to Valenstein, when doctors are driven by "unbridled ambition", "self-deception" becomes "almost impossible to guard against" and the great need for success could "distort facts" with risks being downplayed and "failures" pronounced as "exceptions" (Valenstein 1986:294).

Bharadwaj and Prasad were both critical of the use of conventional binaries, of "right or wrong" in the provision of unproven therapies in India. They instead, drew attention to the transnational "journeys of hope" experienced by international medical tourists treated at Shroff's clinic (Prasad 2015:137). According to Bharadwaj, patients and their families in a "willful" engagement with "seemingly experimental" treatments undergo a "process of experimental subjectification" that "produces both empowering and life-affirming experiences (Bharadwaj 2014:84). The engagement that patients had with hESC therapies also transformed them—like the doctor—into "maverick" agents of "hope and resolve" (Bharadwaj 2014:84), and therefore Bharadwaj argued, these individuals cannot be described as "duped 'medical tourists' " who were "seduced" by the promise of stem cells (Bharadwaj 2014:1103-04). On the contrary, they were empowered actors who sought information largely on the basis of informal communications with other "treatment seekers" (Bharadwaj 2014:86). They were not willing to "sit around in the United States and wait for politics and pharmaceutical companies to sort it out", said a father of a young patient, interviewed by Bharadwaj, in 2009, at Shroff's clinic (Bharadwaj 2014:99).

Bharadwaj's understanding of "experimental subjectification" as an "empowering" process that medical tourists undergo as they knowingly take risks, is similar to how Miller, Novas and Rose viewed the relationship of individuals to their health. The term "subjectification" as opposed to "subject" according to Miller and Rose implied action-oriented individuals taking responsibility for their wellbeing. They are "choosing" subjects (Miller and Rose 2008:8) living in "advanced liberal democracies" capable of exercising their own judgment in situations that they enter by choice, the authors stated (Rose 2007:25). Many medical tourists visiting India belong to nations

that witnessed, from the 1980s onwards, growing ideological and policy support for placing the individual at the centre of his or her life-course instead of the state. In this changed policy framework, citizens are understood not as “universal subjects of government” but rather those seeking autonomy in their daily lives (Miller and Rose 2008:7). According to Miller and Rose, the shift towards a neoliberal form of governance gave rise to “a new ethic” that expects people faced with incurable disease to not despair but instead seize the opportunities offered by advancements in biomedical technologies (Miller and Rose 2008:18). Medical tourists are among those populations that have embodied this changed ethic. They must beat many odds to travel long distances outside their comfort zones in hope for relief from suffering. For a start, they navigate a surfeit of information on the Internet in the form of patient blogs, hospital websites and medical tourism operators offering a variety of medical services and treatment packages. In making the decision to go abroad for stem cell treatments, medical tourists from developed nations also defy “warnings issued by “influential science bodies” that caution against taking chances with experimental therapies provided outside established scientific domains (Petersen, Seear and Munsie 2013:670). According to Einsiedel and Adamson, an estimated 700 clinics provided unproven stem cell treatments, the majority of which were found in developing economies like India, Russia, Thailand, China, Argentina and Costa Rica (Einsiedel and Adamson 2012). In their analyses of 19 medical tourism websites, in 2007, the authors found that the majority advertised autologous stem cell treatments for a range of conditions that included multiple sclerosis, spinal cord injuries, Alzheimer’s and Parkinson’s disease, autism, cerebral palsy and muscular dystrophy (Einsiedel and Adamson 2012). The study also examined patient blogs to find that more than four in ten individuals who had undergone experimental stem cell treatments were children (Einsiedel and Adamson 2012).

According to Mamo, “online direct-to-consumer advertising” gives patients “some degree of physical control through the consumption of certain products or services” (Mamo 2010:176 cited in Petersen, Seear and Munsie 2013:681). This kind of advertising, stated Petersen and others, has “radically transformed” the lay-expert relationship as clinicians have been relegated to one among many sources of medical information (Petersen, Seear and Munsie 2013:681). Harvey who analysed the role of “direct-to-the-consumer” advertising in “genetic testing” argued that such services transform patients into “entrepreneurial citizens” as they are enabled to make the right lifestyle choices in order to prevent disease in the future (Harvey 2010:365). Rose similarly stated that “the Internet has come to provide a powerful

new way in which those who have access to it, and who are curious about their health or illness, can engage in this process of" what he described as "biomedical self- shaping" (Rose 2007:141). An important feature of individuals engaging with their biology via the World Wide Web is the access they are given to personal experiences of patients or caregivers in disease management or the life "strategies" that people adopt to cope with illness (Rose 2007:142). With biomedical advancement in fields like molecular genetics, therefore, also comes a "responsibility" stated Novas and Rose (Novas and Rose 2000:485). Individuals must "inform" themselves and then take the necessary precautions in "the minimization of illness and the maximization of health" (Rose 2007:147). These new platforms that offer people different ways to exercise control over their wellbeing is good news for patients today, according to Rose. The nature of 21st century medical technology has itself changed "the things we might hope for and the objectives we aspire to" (Rose 2007:25). Advanced technologies such as genomics, regenerative medicine, systems biology and other biomedical innovations increasingly demonstrate the ability to manipulate human biology in remarkably fundamental ways, promising to renew, alter or correct our affected biological make-up irrevocably. "The new style of thought that has taken shape in the life sciences", stated Rose, "has so modified each of its objects that they appear in a new way, with new properties, and new relations and distinctions with other objects" (Rose 2007:12). In this shifting biomedical scenario, Rose argued that patients and families no longer have to envisage a life doomed to an uncontrollable "fate" (Rose 2007:51) as current medical innovations not only allow us to hope for dramatic cures but have also transformed the meaning of hope from "mere wishing and anticipation" to "action" and participation in various dimensions of illness (Rose 2007:148).

The literature on hope in the context of healthcare and new or experimental medical technologies is vast. It deserves special attention for it is crucial to understanding how various actors stay interested in experimental medical technologies such as stem cells despite their uncertain clinical and financial futures. The next section focuses on the subject of hope that also permeates the discussion in the rest of the review.

5. The "political economy of hope" in biomedicine

a) The role of patient advocacy groups

Novas defined the "political economy of hope" in "biomedical research" as a "broad field of activity" in which a range of actors with different interests and agendas are interlinked by the promise of biomedical possibility (Novas 2006:289-290). There are patients seeking release from suffering, investors hoping for profitable gains on their investments, scientists needing greater research and career opportunities, clinicians looking out for cures and governments attempting to boost economic growth and leveraging their knowledge sectors for global leadership (Novas 2006; Rose 2007).

Some features key to biomedicine's political economy of hope were elucidated by Novas in his description of the activities undertaken by a genetic advocacy group called PXE international. By keeping abreast of the latest research developments on Pseudoxanthoma Elasticum, a rare genetic disorder, the patient group had developed into an important source of expert knowledge for both clinicians and the public. It also held an important stake in the research process by funding studies and housing a global registry of donated DNA, a highly valued resource for scientists. The registry contributed to the significant discovery of the PXE gene that gave the organisation's founder the designation of "co-inventor of the patent" (Novas 2006:297). Through several licensing deals with laboratories and biotechnology firms, PXE hoped to generate funds from the patent in order to subsidise costs on patient services and have greater control over scientific research (Novas 2006).

The activism of PXE, its outreach methods and the networks it formed in order to gain access to the latest drugs or developments in healthcare research, is not new for patient organisations in countries like the U.S. The distinguishing feature of patient advocacy today though is their highly participatory and dynamic engagement with the state, science and the pharmaceutical industry. According to Novas, lay actors are becoming powerful players in the production of scientific knowledge. They negotiate the terms of uncertainty and simultaneously mobilise the promise of techno-science in order to "act upon themselves to make themselves better than they are" (Rose 2001:18). According to Rose, individual agency in relation to new medical biotechnologies has created a new kind of "biopolitics", different from what Foucault described (Rose 2001:1). Decisions about the health of populations and matters of birth and death, for example, are no longer controlled entirely by political and civic bodies in advanced economies. Managing illness in the current biomedical climate,

includes patient groups like PXE International who have the intellectual and material resources to "not only challenge the authority of biomedical research but also transform the contexts in which it takes place" (Novas 2006:291). Biopolitics today, should therefore be understood by looking at the "aims, methods, targets, techniques" that people use to evaluate themselves and control their lives, believed Miller and Rose (Miller and Rose 2008:7). In this realignment of power occurring in health and biomedical innovation, wealth is also produced in the process, said Novas. He drew from the work of Waldby to argue that the efforts made by PXE International in procuring the patent also produced "biovalue" — indicating how health and markets were inextricably bound together in the political economy of hope (Novas 2006:289). The concept of biovalue was defined by Waldby as the "yield of vitality produced by the biotechnical reformulation of living processes" (Waldby 2002:310).

b) The promise of hESC treatment in India: a conflict between truth and hope

The political economy of hope in biomedicine, in advanced economies, shared common features with the promise of hECS therapy in India, stated Prasad. The point of departure, however, lay in the disruption of the " 'regimes of truth' " that occurred in the practices of unproven stem cell treatments in the country (Prasad 2015:137). The domain of "truth" is characterised by the scientific method, biomedical facts, clinical trials, ethical principles and regulatory norms (Prasad 2015:137). Medical practitioners like Shroff who practiced outside the standard parameters of clinical research, thus, posed a challenge to this regime. Both Prasad and Bharadwaj attempted to provide an explanation for Shroff's practice, situating it within an academic framework rather than dismissing it as mere medical malpractice. According to Bharadwaj, Shroff's clinic, in its confrontation with scientific convention—in other words, the domain of truth—should be understood as an "*undemarcated* space" that offered "alternative epistemic solutions" rather than viewed as unscrupulous practice (Bharadwaj 2014:88). Bharadwaj considered it ironical that academic and policy circles would disregard the positive treatment outcomes experienced by Shroff's informed and largely "Euro-American middle class" patients (Bharadwaj 2014:103). The experiences of medical tourists are dismissed as "placebo, faith healing and desperation", while data from clinical trials using poor Indian subjects is deemed "*credible data*", he argued (Bharadwaj 2014:97). Referring to Sundar Rajan's analysis of India's clinical trial industry as inherently unequal, Bharadwaj argued that vulnerable subjects of clinical trials become "*risked*" in acceptable ways unlike international stem cell patients who, on

the contrary, are the ones with agency to exercise choice (Bharadwaj 2014:97). The acceptance of one type of data and not the other, Bharadwaj argued further, becomes possible through the adoption of universal moral codes such as informed consent that are meant to be implemented in especially designated spaces for established scientific protocols (Bharadwaj 2014). Ong, in her examination of the biotechnology industry in locations across Asia, also argued for a "situated ethics" as opposed to a "universalizing ethical standard" due to the diverse cultural and political contexts within which biotechnologies are developed (Ong 2010:12). On similar lines, Bharadwaj and Glasner stressed the need for developing an alternative in the form of a "liminal third space" within which to analyse the practices of clinicians like Shroff (Bharadwaj and Glasner 2009:81). This alternative space, the authors argued, should not be defined by situating our analysis within limiting categories of a developed North or a developing and unregulated South. Rather, it should be a site that is "open-ended", giving room for "unpredictability", first-time chances and creativity that does not necessarily conform to a "rigid script" (Bharadwaj and Glasner 2009:85).

Murdoch and Scott argued that those who propose an exclusive role for clinical trials in furthering stem cell research are pursuing a "utilitarian" view that could "fall to pieces within the narrowly" defined world of "a patient who has been told they are terminally ill" (Murdoch and Scott 2010:18). To recall Koenig, regulations may have little impact on clinicians who feel morally obliged to offer sick patients the latest or new treatment (Koenig 1988). Moreover, for many clinics, conducting clinical trials may not be an option due to the considerable logistical and financial support required, said Murdoch and Scott. It is this "gray" zone, they believed, that reflects the current status of stem cell science which is essentially "a story of unknowns" (Murdoch and Scott 2010:21). The scientific community therefore needs to recognize "the epistemic reality of uncertainty" that need not preclude a commitment to scientific rigor and patient protection, they argued (Murdoch and Scott 2010:16,21). Unlike Bharadwaj, Murdoch and Scott acknowledged the physical, psychological and financial risks that people have to bear at the hands of unethical providers and proposed the need for greater awareness among patients of fraudulent practices. For this reason, the authors suggested a balanced approach between patient hope on the one hand and regulatory controls on the other (Murdoch and Scott 2010).

Prasad, while arguing that moral arguments are reductive, also simultaneously seemed to indicate discomfort at the stem cell practices of clinicians like Dr. Shroff.

At her clinic there was no systematic method by which to evaluate treatment outcomes, he stated. Positive results could be due to several factors including the placebo effect, and in any case, Prasad reminded the reader, that inconclusive data reflected the uncertainty inherent in the current status of stem cell research and treatment. At the same time, ambiguous results as far as patient perceptions were concerned, did not imply for Prasad that these individuals were incapable of judging how the treatment impacted their health. Rather, the uncertainty indicated "ideological struggles" with the "regime of truth" as patients, Prasad observed, were pulled in "different directions", from the familiar to the strange, from what they heard about clinicians like Shroff and how it converged or differed with their own hopes and fears around the treatment process (Prasad 2015:142). The emphasis Prasad gives to "ambivalence" in patient experiences at NuTech Mediworld and the unscientific practices of the clinic is a point of departure from Bharadwaj's arguments (Prasad 2015:412). Prasad quoted from the blog and published work of one of Shroff's patients to illustrate his argument of a general ambivalence that typified the experience of unproven stem cell treatments. A patient, Amy Scher, who suffered from Lyme disease made the decision to travel from California to New Delhi even though she was fully aware of the polarised views on Shroff that ranged from " 'hero'" to " 'con artist' " (Scher 2013:13 cited in Prasad 2015:142). A PET scan taken after her stem cell treatment at Shroff's clinic had shown the disappearance of a previously existing lesion. In the absence of any other therapy, Scher attributed her recovery to stem cells. In retrospect, however, she reflected on her experience from a wider perspective:

> I now realize that the actual stem cell treatment has become a smaller part of my story than I ever imagined. In the end, it was not necessarily the cure, but the catalyst for my ultimate healing. (Scher 2013:247 cited in Prasad 2015:150)

Similar to Franklin's observations of women experiencing IVF, Scher in the end had stressed the significance of her internal journey rather than the specific clinical outcomes of the therapy.

Dr. Shroff's use of regular diagnostic technologies such as the PET scan and MRI in order to assess treatment results, added credibility to the protocols followed by her clinic, even though, stated Prasad, these evaluations would remain inconclusive in the "absence of scientifically accepted proof" of hESC research (Prasad 2015:148). Prasad also observed that while conventional procedures were used in stem cell

treatments, the clinic's "home-like atmosphere" also made it antithetical to the usually sterile settings of medicine (Prasad 2015:146). A conviviality cultivated with patients, that included the celebration of patient birthdays, made for a friendly clinical environment and an added attraction to many patients who described the clinic as their "second-home" (Prasad 2015:145). Shroff also offered patients a "holistic" healing experience by organising yoga classes and encouraging them to access their personal "power to heal" themselves (Scher 2013:230 cited in Prasad 2015:149). Scher's description of Shroff motivating her patients to take responsibility for their sick bodies and minds was not unlike the research of Good and others on the role of hope in American oncology treatment. According to the authors, hope was provided in "calibrated" steps, with each stage of the treatment involving the encouragement of personal drive and individual will (Good *et al* 1990:72). According to Good and colleagues, underlying the use of hope was the commonly held cultural belief of the interconnectedness between the "psyche and soma" (Good *et al* 1990:75). This meant that having "enough hope" was essential for cancer treatment so "one may *will* a change in the course of disease" (Good *et al* 1990:61). Although hope in this case was mobilised in the provision of relatively known parameters of the disease compared to hESC treatments, both cancer patient and medical tourist shared the uncertainty of clinical outcomes of their treatments. The boundaries between " 'truth' and 'hope' " can therefore be blurred even though they may "never truly be harmonised", stated Moreira and Palladino (Moreira and Palladino 2005:74). The clinical trial representing the regime of truth and hope-driven stem cell therapy both offered patients the possibility of drawing the future into the present moment — through procedures that do not currently guarantee cures.

For Novas, Rose, Bharadwaj and Prasad, new medical technologies provided patients with innovative ways of hoping. In this category of scholarship, engagement with medical innovation was thus seen as an opportunity that empowers patients in their struggle against disease. For Prasad too, despite his ambiguity in describing Shroff's practice, the narratives of patients indicated for him the multiple ways in which knowledge was produced and experienced. Patient journeys of hope, therefore, must be incorporated into mainstream discourse on stem cell research, Prasad argued.

The authors discussed in the following sections have focused on a somewhat different global "biopolitical order" (Waldby and Cooper 2008:59), where "both structural and contingent forces are at play in shaping and constraining these

apparently contingent emergences, making some worlds more possible than others" (Sunder Rajan 2005:28). Hope, in this category of literature, is analysed as a product of industrial strategy and state policy that decides both the substance of hope and its target subjects. The writings of Brown, Michael, Borup and others, for example, that contribute to the "sociology of expectations in science and technology", framed "novel technologies" as not "substantively pre-exist[ing] themselves, except and only in terms of the…expectations and visions" invested in them (Borup *et al* 2006:285). Cooper and Jasonoff showed how new medical technologies have been normalised in western nations as outcomes of institutional and structural forces, driven primarily by economic agendas. Their writings, although focused on advanced liberal economies, are relevant for India with its own neoliberal project and competing interests in the global bio-economy.

c) Hope as strategy: the role of industry and state

> Enthusiasm for medicine's possibilities arises not necessarily from material products with therapeutic efficacy but through the production of ideas with potential although not yet proven therapeutic efficacy. (Good 2001:397)

In a biomedical landscape where stem cells and genes have been successfully commercialised, even hope has become a source of "commodity value", stated Martin and others (Martin, Brown and Turner 2008:127). The significance of patenting a stem cell line, for instance, lies not in its current value but in the hope of it developing into a viable therapeutic source some time in the future. Another case in point is personalised medicine, where hope accrues greater value than the present status of research. In 2011, PricewaterhouseCoopers predicted that the 232 billion dollar market in the area would grow at an annual rate of 11 percent even though tailor-made gene therapies based on an individual's genetic predisposition to disease remain an unfulfilled promise (Vanac 2009; Wade 2010). Highly future oriented market projections such as these are not uncommon for the biotechnology industry that, according to Good, is in the "business of producing ideas about potential therapeutics, from designer anticancer therapies to the manipulation of damaged genes" (Good 2001:397). Since genetic predisposition to a disease is by no means an assured indicator of becoming ill, even presently healthy people are rendered future targets for genetically based therapies, argued Sunder Rajan (Sunder Rajan 2006:175). In this way, Sexton similarly stated, entire populations who can afford new medicines are transformed into ready markets by a health industry that provides

a '"predict and prevent"' form of healthcare (Sexton 2011:1). The notion of preventing illness within this biomedical perspective of health also, therefore, translates into the desire for achieving a "state of optimal wellness" (Harvey 2009:119). The notion of wellness, a subjective state, has been capitalised by a "feel-good industry" comprising self-help books, magazines and online surveys, all of which define happiness and advertise ways of finding it (Ahmed 2010:3). Hence, to achieve happiness, is to follow the path prescribed by the industry and the failure to do so is to deny oneself *"the promise of happiness*" (Ahmed 2010:2). Being happy and well, in other words, is available to only those who have access to different types of resources–"rhetorical, organizational and material" (Novas 2006:292). Without these resources they would be unable to lay a claim on the promise of health offered by new biotechnologies, stated Novas. The patient organisations described by Rose and Novas largely comprised "white middle-class, educated" populations that were "highly capable of mobilizing social networks both in person and through the medium of the Internet" (Novas 2006:302). Although patient advocacy groups represent the entire community, their efforts, Novas stated, could possibly alienate the needs of other sufferers who for various structural reasons have been deprived of access to the same resources (Novas 2006). While Rose and Novas proposed the emergence of a newly found "biological citizenship" for those who have the resources to shape their biological destiny, Brown argued to the contrary (Rose and Novas 2005:439). According to Brown, the "agency" of patient organisations was not entirely constitutive of autonomous individuals acting within frameworks of choice and free will, rather, it was "embedded" in "actual contexts and conditions" (Brown 2003:10).

The biotech industry's appeal to the human "imagination" was "central to brokering new and highly privatized consumption markets in the biosciences", Brown argued (Brown 2005:332). He analysed a substantive "shift away" from "truth regimes" to the "regimes of hope" that occurred in biotechnology debates towards the end of the 20th century in Europe and the U.S. (Brown 2005:332). Debate and discourse previously based on "every-day evidences, proofs, facts or truth" was overshadowed by the increasing use of "future oriented abstractions premised on desire" and "imagination" (Brown 2005:331). Brown illustrated his arguments with the example of private cord blood (CB) banks—that store umbilical cord blood belonging to paying clients—claiming to offer services for "future treatments" that are "both real and imagined (but mainly imagined!)", he said (Brown 2005:341). Current realities on CB stem cell research are easily lost in advertisements by cord blood banks using "websites and glossy brochures" depicting "happy parents" and "ideal families" as outcomes of their

decision to store their new born baby's cord blood (Brown 2005:341). The facts on cord blood stem cell treatments, however, tell a different story: "unless the family has a history of blood disorders, there is only a one in 20,000 chance that the infant will need her own blood during her first twenty years of life" (Dickenson 2008:51-52). Even so, in the case of blood conditions such as leukemia and other blood cancers, autologous (your own) cord blood may not always be suitable as it could be the very source of the cancer or disorder itself and "might well reintroduce cancerous cells back into the body, even after their successful removal during chemotherapy" (Brown 2005:341; Dickenson 2008). Moreover, a single sample of cord blood will most likely be inadequate for an adult patient (Dickenson 2008).

The facts on stem cells in cord blood have also not deterred private CB banks in India from creating "economic value by capitalizing on the hopes of parents…" (Martin, Brown and Turner 2008:141). After the U.S., India is among the world's largest storehouses today of private cord blood (Hodges 2013:5). By designating cord blood as "waste", private banks easily justify the market potential of the biological material (Hodges 2013:8). According to Hodges, who studied the relatively "recent surge in popularity" in CB banking in the city of Chennai (South India)[3], private banks use marketing strategies in "highly structured…ways" even though the practice is "unregulated" (Hodges 2013:6). Similar to advertising practices the world over, CB banks in India also promise "expectant families" protection of "their unborn child against the perils of the future and its unknown" (Hodges 2013:7). Hodges learnt from a "cord blood stem cell banker" that the difference, however, in marketing strategies of CB banks in India is targeting the "joint family" as opposed to the individual parent (Hodges 2013:7). Apart from CB banks promoting services through clinicians and the health system, Hodges finds that most of the hard selling by banks occurred within the home. Involving the extended family in the decision to invest in

[3] It is important to mention that despite the popularity of CB banking in Chennai, Hodges encountered "interruptions" in the narrative of "uptake", of the practice (Hodges 2013:1). These "interruptions" occurred in the form of resistance to CB banking due to the co-existing belief of cord blood imbued with "supernatural" powers that can cure infertility and also protect children from the "evil" eye (Hodges 2013:11). Some families did not buy into the idea of CB storage for the fear of the precious resource falling into the hands of strangers. Their response "complicates" the marketing strategy of banks describing cord blood as a useless material after childbirth (Hodges 2013:13). While these "interruptions" have not prevented the industry's growth, they have "rendered precarious", said Hodges, the narrative of "accumulation" in the context of the "body" and "globalization" thereby demanding a "constant re-constitution" of the workings of accumulative practices within and outside the contexts of new markets (Hodges 2013:15). As the popular narrative gets broken in parts, it also simultaneously consolidates the "ways in which the body" is further embedded in "multiple practices for the extraction and accumulation of wealth", Hodges concludes (Hodges 2013:15).

the future health of the new baby by storing the infant's cord blood was a strategy that "sits well", said Hodges, with the cultural notion of the "joint family" as the upholder of "biological and financial" continuity (Hodges 2013:7). The CB banks also maintained that relatives might benefit from cord blood storage, a highly misrepresented claim as even in the case of a "sibling" there is only a "25 percent chance" that the cord blood will be usable (Hodges 2013:4).

According to Brown and Michael, "If the practical utility and value" of a medical technology "has yet to be demonstrated", the expectations invested in that technology take on particular significance (Brown and Michael 2003:3). The nature of these expectations could although vary among actors, depending on their temporal and spatial relationship with the technology. For instance, expectations among patients who "see themselves as having little" control "over the outcome of a promise" might assume "the appearance of greater authority" as compared to scientists who are likely to be more skeptical (Brown and Michael 2003; Borup *et al* 2006:292). Capitalising on the vulnerability of lay actors and making their choices seem like independent actions was, thus, easy for the industry, these authors argued. The CB banking industry like the wellness market has created an obligatory kind of hope, stated Brown, "where failure to invest" could result in "moral recrimination later" (Brown 2005:344). Similarly in the case of IVF, Franklin described how it became harder for women to stop the treatment the further they had progressed for the fear of "abandoning hope" and giving up on a dream that could be "only one step away" (Franklin 1997:12). The perfect fit of emerging biomedical markets with political and ideological orientation towards individual responsibility and choice was no coincidence in developed western economies, Cooper argued, but rather a product of calculated policy decisions taken in the 1980s and thereafter (Cooper 2008). The section below explores, with greater focus, the scholarship that looks at the role of policy in the development of a medical biotechnology industry and the sector's growing significance in national and global economic agendas of nations worldwide.

6. The normalisation of biomedical innovation: the role of state policy

a) Advanced industrialised economies

Faced with a fiscal crisis in the 1980s, industrialised nations such as the U.K. and the U.S., saw in the life sciences an untapped commercial potential that could be used in revitalising their lagging economies (Cooper 2008). Groundbreaking biomedical

innovations of the 1970s such as recombinant DNA, not initially meant for commercial use, later provided opportunities for investment and alternative sources of capital (Tyfield 2010). New and landmark legislations such as the U.S. Bayh-Dole act of 1980[4], paved the way for closer ties between academia and industry in conducting scientific research with potential for product development. According to Birch, the idea of a knowledge sector essential to economic growth emerged from an "expansion of specific economic discourses and practices" that linked the goals of "innovation, growth and competitiveness" (Birch 2006:3-6). Jasonoff also argued that the distinctive feature at this juncture in biotechnology's history was its growing association "with economic and political power" (Jasonoff 2005:5-6). This reorientation in objectives for investing in biotechnology research that occurred had undermined its potentially neutral role in society, she said (Jasonoff 2005).

Between 1975 and 1995, both agricultural and medical biotechnologies entered private markets in an atmosphere of cautious optimism. Advanced industrialised nations of Europe and North America that had set in motion new laws and regulations to streamline research and its easy commercialisation, had hoped that any risks posed by new technologies were "well understood" and "manageable" in order to be accepted by policy makers and the public (Jasonoff 2005:94). By 2001, fierce debates and controversies on stem cell research and genetically modified foods were clear signs that the future envisioned for a new era of biotechnology was not quite as unencumbered as its early proponents might have envisioned. In comparing the development of biotechnology industries in Germany, the U.S. and the U.K., Jasonoff described the "different", and not always successful, "national strategies of normalization" these three countries adopted in order to make "human biotechnology seem mundane and governable in the face of moral uncertainty and conflict" (Jasonoff 2005:147). In the inextricable link between biotechnology and "projects of reimagining nationhood", the role of specific actors and events, she stated, was crucial in embedding techno-science within existing systems and also creating new ones (Jasonoff 2005:7). The judiciary in the U.S. for instance played a

[4] The Bayh-Dole Act allowed government supported research in universities, non-profit institutions and small business to patent their discoveries and grant licensing rights to the industry to market the product and pay royalties to the inventor (Angell 2004). Before the legislation a public funded discovery was available to any company for use. Since the passing of the Act the number of patents granted to universities had risen from less than 300 a year to more than 3000, allowing a U.S. university to earn up to two billion dollars a year, whereas prior to the Act financial benefits to a university from licensing were negligible (Sampat 2010: 755).

prominent role in validating the commercial viability and safety of new biotechnologies. Using the example of the Diamond v. Chakrabarty case, Jasonoff illustrated how existing laws in the U.S. were used to define medical innovations as significantly new to set landmark precedence, but also normal enough to not warrant conditions of exceptionality, thus, facilitating easy and quick adoption of new technologies. In this case, a genetically modified bacterium developed by scientist Chakrabarty was defined as man-made because it had been modified by human intervention. By this definition, the product could qualify for patenting like any other, and simultaneously it could also claim the existing patent criteria of novelty, usefulness and non-obviousness as the invention was also unlike its natural counterpart. This case argued in the U.S. Supreme Court, in 1980, had far reaching implications for the biotechnology industry with regard to the patenting process. A patent was granted on a living organism for the first time in the history of patent law, only made possible, Jasonoff argued, because the judiciary had strategically manipulated the meaning of the novel and natural in biotechnology. The court, on the one hand, declared the entity as "not so radically new that it fell outside the range of things that Congress had defined as patentable", and on the other hand, it claimed human ingenuity to justify newness in the features of a naturally occurring organism (Jasonoff 2005:210). The genetically altered organism was, thus, sufficiently novel for being patented but also ordinary enough to not cause concern. The ruling paved the way for further commercialisation of other life forms. "Being ' "first" ' was important for the U.S., stated Jasonoff and nowhere was the link between science and "national goals" more apparent than in the country's health biotechnology policy (Jasonoff 2005:234).

The framing of biotechnology as a product was not quite so straightforward in Britain, Jasonoff finds. Despite the country's strong commitment to the industry, it was more "cautious" in proclaiming the market potential in biotechnology (Jasonoff 2005:55). The effects of " 'mad cow disease' " had been "traumatic" for the country and there were real fears around the release of genetically modified organisms into the environment (Jasonoff 2005:56). British experts, the dominant voices in the 1980s, argued that the "uncertainty" and "unpredictability" of biotechnology should guide Britain's policy rather than a complacent assuredness of its benefits (Jasonoff 2005:57). Germany, on the other hand, coped with challenges unique to its historical narrative. Public memory and opinion on science and technology was deeply rooted in the horrors of the holocaust, making participation from political groups and social movements in the formation of regulations even more urgent and necessary than in

the U.S. or U.K. Ultimately, the efforts made by these nations to achieve normalisation as an "ordering mechanism" by which biotechnologies would be introduced into society without controversy or fear, was a tenuous process, Jasonoff discovered (Jasonoff 2005:95). Normalisation strategies were not effective enough to withstand recurring controversies of new scientific developments such as hESC research. Volatile debates on using human embryos for stem cell research reached the highest levels of state policy in many countries. The "Great Embryo Debate" in the British parliament took place shortly before an Act on hESC research was presented in 1989-1990 (Mulkay 1993:721). Mulkay analysed how "two rhetorics" — one of "hope" and the other "fear", played out during the debate (Mulkay 1993:721). The "rhetoric of fear" presented a dire picture of technological change as it recalled fictional depictions of moral and social "disorder" wrought by technology's intervention in the human body (Mulkay 1993:736). In contrast, "at the heart of the rhetoric of hope" was "an idealized vision of the relationship between science and society" (Mulkay 1993:728). Supporters of "hope" imagined "a radically simplified future where scientific knowledge" would provide all the solutions to disease without "consideration of social change" (Mulkay 1993:728). Mentioned earlier in the writings of Brown, the "rhetoric of hope" also emerged victorious in hECS debates, winning over Britain's policy makers and giving its scientists one of the world's most liberal regulations on hECS research (Mulkay 1993:728). Franklin similarly wrote about the state's contribution in making IVF a "hope technology" (Franklin 1997:203). Metaphors of hope were not only the media's domain, she argued, but also belonged to British parliamentarians, for whom, the "biological model of 'the facts of life' " had proven inadequate and the "language of…miracles" was preferred in proposing state support for assisted reproduction (Franklin 1997:200).

In this promotion of "regimes of hope" by state and non-state actors, there emerged an important ally in the form of bioethics (Brown 2005:332). By the 1980s, the discipline had developed into a useful political tool for fledgling knowledge economies that realised the need for a new ethical framework for biomedical research using human subjects. Existing systems were proving ineffective in strengthening the fragile relationship between state, science and citizen, and bioethics with its "promise of bringing order and principle to domains previously governed by irrational, emotive…reactions", was seen by state and industry as a trustworthy interface between key actors in biomedical research and development (Jasonoff 2005:172). The major role that the discipline assumed, critics argued, fell short of what its supporters had envisaged for it. Jasonoff and Bosk both write about

bioethics failing to achieve its objective of balancing the interests of science with human values and instead coming to the aid of "organized medical interests" (Bosk 1999:62). Bioethics today is an active player in the oversight of biomedical research, the world over. The uniform application of bioethical principles such as informed consent and patient autonomy for every problem in scientific research has resulted in the individualisation of risk and the overshadowing of structural contexts that subjects occupy (Bosk 1999; Jasonoff 2005). For the industry, this cookie cutter approach to the protection of human subjects has required little effort and is easily applied. In the specific instance of stem cell research, Salter and Salter explained how an "active moral economy" has become necessary to legitimise the highly globalised network of hESC research still plagued in some countries by cultural and religious "resistance" (Salter and Salter 2007:555). Ethical guidelines for conducting stem cell research have been developed across the world, including in Asian countries that have also invested state funds in biomedical innovation. For example, India's national guidelines on stem cell research in particular and biomedical research in general, follow universalised bioethical principles that are applied as standard frameworks to evaluate the ethical conduct of scientific research using human subjects. Using globally accepted guidelines for conducting research in controversial areas such as stem cell research was one of several steps taken by Asian countries, including India, to build biotechnology sectors that were worthy of inclusion in the global knowledge economy (Thompson 2010). Major shifts in policy and ideology that occurred "around innovation and competitiveness" in the "bioeconomy[5]" of advanced liberal economies such as the U.S., also "had an enormous influence on other countries", stated Birch (Birch 2006:7). The following section discusses the literature on biotechnology policy in Asia with a focus on India and its stem cell initiatives in particular. It examines how countries like Korea, Singapore, China and India have supported a biotechnology sector with the overall objective of advancing the national economy and also acquiring a share in the global biomedical pie.

b) "Biotech nationalism" in Asia: an India focus

Ong described a "biotech nationalism" also prevalent in Asia (Ong 2010:23). Investment in the life sciences by Asian governments were very much "aligned with nationalist projects" and a desire to participate in the global "biotech revolution", she

[5] A knowledge economy or bio-economy is defined by the Organisation for Economic Co-operation and Development (OECD) as: "the aggregate set of economic operations in a society that use the latent value incumbent in biological products and processes to capture new growth and welfare benefits for citizens and nations" (OECD 2006:1 cited in Gottweis, Salter and Waldby 2009: 26).

stated (Ong 2010:3-5). In Thompson's opinion, fraud committed by South Korean stem cell scientist Hwang Woo-Suk, was an act of desperation for this global recognition as much as it was a crisis in South Korean science (Thompson 2010). Hwang was accused of falsifying facts and also coercing his laboratory assistants into donating their eggs for stem cell research. The egg donors, contrary to world outrage, continued to support the defamed scientist. The actions of these women, according to Thompson, represented a defense of Hwang's "Koreanness" rather than a cover up of unscrupulous research (Thompson 2010:112). In a comparative study of stem cell research between Singapore and South Korea, Thompson found that although advancing nationalist goals was a common objective for both countries, their outlook towards biomedical innovation was different. Unlike South Korea's relatively insular orientation, Singapore was more "internationalist" in its organisation and research ethos (Thompson 2010:97). The latter's biomedical complex called "Biopolis" looked like an "expensive new", "real estate" "development" that was concerned with finding the "right kinds of people" from all over the world, Thompson described (Thompson 2010:109). A mix of private and public sector laboratories, some of them run by "high status researchers from overseas", Biopolis conducted research with strict adherence to international ethical standards (Thompson 2010:110).

With regard to India, a review of the country's state policy documents and private sector reports on science and technology, revealed the familiar rhetoric—of national progress, global expansion and "inclusive growth"—that also informed biotechnology policy of other nations (Ministry of Science and Technology, GOI 2013:1). In addition to biotechnology's historically envisioned capability of nation building and alleviating India's social ills, the sector today is also expected to achieve goals—of "global competitiveness" and science leadership—that extend beyond national developmental concerns (DBT, National Biotechnology Development Strategy, GOI n.d). India's Department of Biotechnology envisions "shaping biotechnology" for "ensuring social justice–specially for the welfare of the poor" while also describing it as a "tool" for the "future…creation of wealth" (DBT, Vision, GOI n.d.para.1). In "attainting new heights in biotechnology" (DBT, Vision, GOI n.d. para.1), the department includes in its "development strategy" the objectives of "building world class human capital", supporting the creation of "competitive enterprises", "generating intellectual property in frontier biotechnologies" and accessing global markets (DBT, GOI, n.d.:2-3). According to DBT's annual report of 2009-2010, India needs to be "more competitive" in the life sciences by promoting "innovation and

entrepreneurship" (DBT, GOI 2009-2010:1). Other documents published by India's department of science and technology (DST) also declared lofty goals for Indian science. In 2010, the Science Advisory Council to the Prime Minister, published a document titled, " 'India as a Global Leader in Science' " (DST, GOI 2010:3). It described India's great potential for scientific advancement but the country's various "strengths" have remained under utilised, the Council stated (DST, GOI 2010:5). The areas in science and technology that the DBT Strategy document described as "vital to India's progress, but in which current strengths are suboptimal" were "stem cell engineering and regenerative medicine" among others (DBT, GoI n.d.:8-9). Stem cells, with their transformative potential for health, science and industry, get important mention in DBT documents. The department's 2009-2010 annual report describes stem cell research as an "exciting field of life science" (DBT, GOI 2009-2010:93). By 2007 the DBT had supported over 30 stem cell projects associated with the liver, heart, limbal and neural cells and as well as hESCs (Salter *et al* 2007). The 2009-2010 annual report also mentions the Institute for Stem Cell Biology and Regenerative Medicine (inStem), in Bengaluru, as an "upcoming institution" supported by the DBT (DBT, GOI 2009-2010:173). Today, inStem is India's premier research institute in the field. Its establishment occurred during India's Eleventh Five Year Plan (2007-12) that was important for the biotechnology sector and stem cell science in particular (DBT, GOI 2006). The Plan period saw a substantial increase in collaborative arrangements and public-private partnerships that the DBT considered significant for promoting global competition and increasing commercialisation of biotechnology (DBT, GOI 2006). Several major initiatives to promote basic and applied research were undertaken during this period, which included the building of new autonomous research institutions under the DBT such as inStem.

A report prepared in 2012 for the DBT by the Association of Biotech Led Enterprises (ABLE), lists several public and private institutions in India that are associated with stem cell research (see appendix for institutions). The report titled, "Indian Biotechnology: The Roadmap to the Next Decade and Beyond" mentions stem cells among the "frontier areas" of biotechnology (ABLE 2012:4). It categorises the various establishments associated with stem cells on the basis of the kind of stem cells used that include embryonic, limbal, neural, cardiac, muscle, mesenchymal, bone marrow and liver stem cells. The institutions conducting research/treatment and or developing therapies—and also housing stem cell banks in some instances—include publicly funded, autonomous research institutes, public and private hospitals and private firms involved with stem cell product development. Among the private

enterprises mentioned by ABLE is Reliance Life Sciences in Mumbai that has widely publicised its interest in the field of stem cell research. In 2001, *The Business Standard* announced the company's filing of a 'provisional patent' with the U.S. patent office in the area of embryonic stem cell research (Baburajan 2001). In 2008, the magazine *BioSpectrum* reported the firm's intention to develop a "wide range of novel research-led, autologous and allogenic stem cell therapies and tissue-engineered products to get into [the] regenerative medicines business" (Parveen 2009). In 2010, *India Today's* cover story on stem cells quoted the firm's President and CEO, K.V. Subramaniam's grandiose statements on the field's future: "in just about two years, about 164 million patients, or 16 percent of India, suffering from diabetes, cardiovascular disorders, neurological disorders, burns and wounds, osteoarthritis, osteoporosis and liver disorders would benefit from stem cell therapies in India" (Chengappa 2010:52). The piece also mentions the DBT having invested over 300 crores in the stem cell field and quotes the department's secretary in whose opinion a " truly 'mass revolution' " in stem cell science in India is only possible with the involvement of the "industry" (Chengappa 2010:52). Lost in this puff piece on the future promise of stem cells is a contradictory message by the CEO, advising caution in raising expectations on stem cell therapies on account of the problem of "scalability of treatment" (Chengappa 2010:52). The other private stem cell firm mentioned in the ABLE report is the Bengaluru based, Stempeutics Research Pvt. Ltd. (ABLE 2012). On its website, Stempeutics is described as a "late stage life science company focused on developing and commercializing novel therapeutics based on adult stem cells". Its "vision" it said, was "to transform medicine and offer new hope to millions of people". In 2009, Stempeutics formed a "strategic alliance…for marketing its products" with Cipla, India's well-known pharmaceutical company (Stempeutics Research Private Ltd. 2006).

According to the ABLE report, India's biotechnology sector was valued at four billion U.S. dollars in 2011, a six-fold increase since 2003 (ABLE 2012:11). In the same year, the Ernst & Young Global Biotechnology Report stated that India's biotechnology industry "with increased financial assistance and opportunities" continued "to make progress" (Ernst & Young 2011:31). With regard to India's market capacity in regenerative medicine in particular, the ABLE report was restrained in its future projections (ABLE 2012:36). India does have the "potential to emerge as a global leader" in biotechnology, the report stated, but it still "has a long way to go" in developing new medical technologies such as those in regenerative medicine (ABLE 2012:36). Relatively reserved assessments of India's biotechnology sector are

overshadowed by high optimism, amounting to hubris that pervades policy documents describing the country's future status in science and technology. In 2013, the Science, Technology and Innovation (STI) Policy, for example, like other policy statements before it, stated its ambitious goal for India's inclusion in "the top five global scientific powers by 2020" (Ministry of Science and Technology, GOI 2013:4). Among the other components of the STI policy were: "enhancing skills…among the young", "making careers in science…attractive" and "establishing world class infrastructure for…gaining global leadership in some select frontier areas of science" (Ministry of Science and Technology, GOI 2013:4).

Structural adjustments made to India's economy in the 1990s "are changing the scientific scenario…dramatically", stated the Advisory Council's 2010 document (DST, GO1 2010:11). The document described the period of economic reforms as significant in the country's history, equal in "magnitude" only to the initiatives of Nehru's government in newly independent India (DST, GOI 2010:11). The "strides" made in the reform period were thus expected to "presage a new way of investment…in science" by public and private players, the document stated (DST,GOI 2010:11). India was one of the "first developing countries to recognize the importance of biotechnology", said Lofgren and Benner (Lofgren and Benner 2010:169). By 1982—when significant developments were taking place in biotechnology abroad—India had formed a "coordinated" biotechnology policy (Lofgren and Benner 2010:169). Later in the 1990s, the health biotechnology industry was given a major boost when the economy undergoing structural adjustments opened several sectors to private enterprise, international capital and global markets. In 1996, by signing the Trade Related Intellectual Property Rights Agreement (TRIPS), India also committed to applying international patent laws in research and development. The signing of TRIPS, critics argued, meant the "abandonment of self-reliance" in India's indigenous pharmaceutical industry (Lofgren and Benner 2010:168). Compliance to global intellectual property rules would undermine the country's successful generic drug industry, producing relatively low cost drugs compared to expensive patented ones. Post-TRIPs, India's publicly funded research laboratories were given the mandate to prioritise those areas that were marketable and patentable but not necessarily compatible with the country's epidemiological needs and concerns (Lofgren and Benner 2010). The term, innovation, Sunder Rajan similarly argued, did not necessarily imply original and inventive research for India's public health needs. Rather, it meant a research "orientation" that looked at international markets and expressed a "desire to be like

the global Other" (Sunder Rajan 2006:192). India signing TRIPS, thus, symbolised, said Sunder Rajan, the ultimate "imitation of an American culture of innovation" and represented the nations "post-1990s determination to become a major player in the global market system" (Sunder Rajan 2006:188-189).

State incentives given to corporate sector investment in India's healthcare in the 1980s-1990s and the overall intensification of privatisation of the health sector worked in tandem with developments like TRIPS that were influenced by both global shifts and changing priorities in internal state policy. By the mid-1980s, 50 percent of outpatient services across India were provided in the private sector and by mid-1990s the figure increased to 72 percent in urban India and 64 percent in rural regions (Baru 2006). In the 1990s, the growth of India's health sector had shown a yearly compound rate of 16 percent and today it is one of India's largest employers and revenue earners (Bisht, Pitchforth and Murray 2012). In 2017, the healthcare industry was expected to be worth 160 billion USD and projected to reach 280 billion USD by the year 2020 (India Brand Equity Foundation 2017). Medical tourism was an important revenue earner for India's healthcare sector. In 2015, The *Economic Times* reported the medical tourism market at the current value of three billion USD expecting to reach eight billion USD by 2020 (The *Economic Times* 2015). Its growing influence in the healthcare sector was not an outcome of "international influences alone", stated Qadeer and Reddy, but also the result of changes in internal policy priorities (Qadeer and Reddy 2013:2). India should become a " 'a global health destination' " said the finance minister during an annual budget speech in 2003, indicating the government's unequivocal support to the growth of medical tourism in the country (Qadeer and Reddy 2013:2). As "free trade principles are applied to services as well as commodities", Whittaker, similarly argued, that international agreements together with internal or national reforms "encouraged the privatization and commercialization of health care systems across the world" (Whittaker 2008:275).

Corporate hospitals in India were instrumental to the growth of India's medical tourism industry and promotion of high-end medical technologies. These institutions promised "high quality" treatments provided by "the best medical staff you can dream of", stated Lefebvre (Lefebvre 2008:90). "The recognition" they received "from abroad" also helped "improve their image among the local population" (Lefebvre 2008:96). This population, Lefebvre noted, was not "the general" public, however, but "the high and higher middle income population" of India or those who could afford the

high rates[6] of the corporate sector (Lefebvre 2008:90). While the bigger hospitals clearly had greater purchasing power to import the latest medical equipment, today there is a range of private institutions that claim to offer the latest medical technologies (Baru 2005). The "newfound sense of entitlement" found among "affluent Indians" post "market reforms" informed their "attitudes" on "consumer choice", said Hodges, in the context of cord blood banking in Chennai (Hodges 2013:5). The cord blood business also functioned on a "corporate health-care model", marketing their services within similar tropes used by the corporate health sector — of expensive "high quality, high-tech" infrastructure as symbols of "national pride" and India's " 'arrival' " into modern and contemporary ways of living (Hodges 2013:5). According to Hodges, despite the uncertainty around cord blood stem cell treatments for non-established conditions, the industry has been successful as it "bears the hallmarks of post-liberalization India" (Hodges 2013:5).

Experimental stem cell treatments and cord blood banking are recent additions to the repertoire of healthcare technologies offered to paying clientele in the country. Several tertiary care hospitals and research centres in India offer unproven stem cell treatments (Patra and Sleeboom-Faulkner 2009). Some of these hospitals are in the public sector but most are private sector establishments. They offer stem cell treatments "under the ambiguous guise of experimental therapy" but in actual fact have profited from it, stated Patra and Sleeboom-Faulkner (Patra and Sleeboom-Faulkner 2009:148). On the basis of their study on (mostly adult) stem cell treatments in India for unproven conditions, they introduced the concept of "bionetworking" that involved collaborations among large healthcare institutions, smaller hospitals, clinics, patients and individual physicians (Patra and Sleeboom-Faulkner 2009:147). Since these "bionetworks" encompassed healthcare providers across sectors and also included associations abroad, the "distinctions" between the "private and public", the local and the global were opaque in unproven stem cell provision (Patra and Sleeboom-Faulkner 2009:147,152). The networks functioned using a " 'hub and spokes model' ", explained Patra and Sleeboom-Faulkner, with the larger hospitals linked with smaller healthcare providers, both in the country and outside (Patra and Sleeboom-Faulkner 2009:151). Among the networks they studied, for example, was a "private enterprise" in Chennai, Tamil Nadu, comprising several hospitals that they referred to as the "X Group of Hospitals" and another group in

[6] For example, the price for a coronary angiography that requires an entire day in the hospital was rupees 13,000 in the general ward of a corporate hospital, compared to rupees 5,000 charged by the All India Institute of Medical Sciences (AIIMS) in the public sector (Lefebvre 2008).

Bengaluru, Karnataka, called the “Y Group” (Patra and Sleeboom-Faulkner 2009:151-152). Both groups comprised several institutions, and “under” these large conglomerates, separate “commercial” entities offering stem cell therapies were also established (Patra and Sleeboom-Faulkner 2009:152). These entities or companies forged their own domestic and international collaborations, thereby creating networks involving an intricate web of institutions, partnerships, activities and actors. According to Sleeboom-Faulkner and Patra, the extensive connections and influence these larger healthcare enterprises wielded, allowed them to outsource “illegal therapies to smaller hospitals hidden in the dense connection networks of large private hospitals” (Sleeboom-Faulkner and Patra 2011:280). Advantageous to these connections was the relatively “low” operational cost in healthcare provision in India, and even expenses on regulatory permissions, legal and other bureaucratic procedures, could “be kept to a minimum” (Patra and Sleeboom-Faulkner 2009:148).

Among the main tasks of a bionetwork was finding patients from India and abroad. The process of recruiting was usually covert since stem cell treatments were offered even when “medical conditions do not warrant it” (Patra and Sleeboom-Faulkner 2009:153). The “confusion” that usually surrounded the provision of stem cell research and the easily manipulated definitions of research and treatment worked in favour of bionetworks (Sleeboom-Faulkner and Patra 2011:647). The providers took advantage of inherent “ambiguities” and uncertainties and unlike in the case of clinical trials “where there usually is clarity about the experimental nature of therapies”, the bionetworks were not compelled to prescribe to standard study protocols (Sleeboom-Faulkner and Patra 2011:647). According to the authors, patients within India entered networks through referrals and also of their own accord, with some being informed through media sources. They were usually from the “upper-middle and upper economic strata”, and those who travelled from different parts of country for the treatment usually belonged to “business families, high position public servants and private sector executives” (Patra and Sleeboom-Faulkner 2009:158). For instance, the former chief minister of the state of Chattisgarh was Dr. Geeta Shroff’s patient, whose claim of improvement in his paralytic condition was widely reported in the media (Bisserbe 2010). Patients or caregivers were “often knowledgeable” individuals, stated Patra and Sleeboom Faulkner, who had faith in new medical technologies. Even physicians who profited from their stem cell practice “may be full of hope and dedicated to their research”, said the authors (Patra and Sleeboom-Faulkner 2009:160). The “lopsided interdependencies” found among various “stakeholder[s]” in stem cell provision and

also occurring in India's healthcare in general, along with the regulatory discrepancies between countries, were all essential ingredients to the success of a bionetwork (Patra and Sleeboom-Faulkner 2009:148). The widespread "commercialisation of health" without which the bionetworks would not have been possible also implicated the state in "indirectly" supporting the 'bionetworking' practices of therapy providers", argued Patra and Sleeboom-Faulkner (Patra and Sleeboom-Faulkner 2009:147).

Patra and Sleeboom-Faulkner's research on the practice of unproven stem cell treatments in India, recalls the writings of Burns on the important role played by networks and social relations in developing and diffusing new medical technologies. According to Burns, "social actors—private and public, individual and collective—play the role of entrepreneurs" (Burns 1985:85-86 cited in Blume 1992:59). They also create "the new" by building "on experiences" of what is existing or already known, he stated (Blume 1992:59). Patra and Sleeboom-Faulkner in their investigation of local and international bionetworks and the conditions that facilitated network activities significantly widened the epistemic terrain of stem cell experimentation in India. Literature on experimental stem cell treatments in the country is limited and the anthropological scholarship of Patra and Sleeboom-Faulkner stands in contrast to the ethnographic research of Prasad and Bharadwaj who provide a largely micro picture of the subject. Bharadwaj's arguments were primarily centred on situating Dr. Shroff's unregulated practice within a niche academic space, to the exclusion of the many structural dimensions that have enabled the routine provision of hESC treatments and also allowed practitioners to make a successful business of human medical experimentation. Both Prasad and Bharadwaj in their emphasis on the subjective experience, whether in the context of the doctor or patient, have clearly done justice to the significance of the personal narrative. At the same time, however, in glorifying individual agency, the discrepancies and irregularities in relationships between state, science and the individual are lost, and inadvertently so is the power and reach of the individual narrative been diluted. "Patients for whom current therapies are not effective will always be with us, suffering conditions that seem to justify risk, yet", said Valenstein, "their treatment may be determined by factors other than their own welfare" (Valenstein 1986:294).

It can be argued that Bharadwaj and Prasad in studying the "phenomenal forms of everyday life" without an in-depth analysis of historical contexts and broader social processes, were only conforming to the methodological and theoretical expectations

of their field or to the choice of research method (Sharp 1982:48). Ethnography gained importance in order to "rediscover the individual as an active creator and constitutor of the social world" stated Marxist scholar, Sharp (Sharp 1982:60). Even so, she argued, ethnography is limited because it functions on the assumption of "methodological individualism"— that only "individuals really exist" and only they can create their reality through "social construction" (Sharp 1982:49). By "social construction", Sharp meant the production of subjectivity through an individual's thoughts, feelings and daily routines that are then "maintained" by him or her as "real" (Sharp 1982:49). By arguing for expanding ethnography's reach to producing knowledge beyond what is observed or understood of that observation, is not to diminish the role of subjectivity in understanding a particular phenomenon, said Sharp. Rather, this way of producing knowledge obscured the fact that human beings "are born into and are socially constituted by a world already made" and consisting of "structured patterns of social relations" that "preexist the individual" (Sharp 1982:49-50). More recent critics of ethnography include those from within the field like Thompson, who also recognised the shortcomings of investigating specific locations without equal attention to the broader political, socio-economic contexts that also influence and give meaning to individual actions and events (Sharp 1982; Thompson 2005). Thompson pointed to the overemphasis by "some biomedical theorists" on "the role that is played by experience" (Thompson 2005:17). The clinic, she argued, combines "lives and technology" and thus researchers must caution against excessively privileging "technology" or "experience" (Thompson 2005:17).

This thesis draws heavily from Franklin and Thompson's ethnography on IVF. Their research provided an analytical framework for the study's findings and also gave it conceptual clarity. In addition to the definitions these authors provide on normalisation, Thompson, for instance, also explained why STS scholars are often misunderstood due to their social constructionist influences, an approach commonly defined as the denial of reality. The term "construction" Thompson argued, is to "attribute reality and causal power to many ontologically different kinds of things and to many different kinds of agents" (Thompson 2005:33). This is quite different, she stated, from the perception of "reality denying" (Thompson 2005:33). Thompson's research on IVF was, thus, about understanding the "intersection between subjectivity and technology" (Thompson 2005:17). There were "more people" in her account than a typical STS study since "narratives of the self are important in fertility", she said, and not because her objective was to focus on the "lives of infertile women and men or of clinicians per se" (Thompson 2005:17).

This study too, is dense with the voices of patients, caregivers and providers. Similar to the scholarship of Bharadwaj and Prasad, it recognises the intensely personal accounts as integral to investigating an actor's relationship with a biomedical technology and medical experimentation. Simultaneously, the study has also attempted to contain within these highly individualised frames, the broader realities that have influenced private and professional lives. In other words, the personal narratives of this study have been directed not as an end in themselves or to prove the supremacy of subjectivity, but rather they have been used as a lens with which to view both the every-day life that patients and providers inhabited and the larger forces that might have shaped it. The study's findings have raised issues of state policy that are relevant to and associated with existing problems of healthcare policies, scientific research, clinical trials and other related developments. These are concerns rooted in structural shifts and policy choices, and the normalisation of stem cell experimentation is argued as yet another, albeit extreme, example of healthcare commercialisation. From the study's findings, the emergence of a new phenomenon—the largely urban, middle class experimental subject population— is also revealed. An analysis of this type of experimental subject departs from the existing discourse on medical experimentation in India and raises questions about the possibility of new precedents being set in healthcare practice and medical experimentation in the country. Discussed in the chapters to come, all of these issues emerge in the context of normalisation of stem cell experimentation, highlighting concerns that extend far beyond the experience or control of individuals.

7. Situating the study

Many of the structural, institutional, and individual dimensions to the normalisation of stem cell treatments in India were not unique to the medical technology or the country. Rather, the normalisation pathways, once again, make a case of lessons unlearnt or unheeded in the use of new biomedical technologies, regardless of time or location. The historical continuity of factors in the widespread diffusion of experimental medical technologies is unmistakably evident in this study. Much of the literature on the routinisation or normalisation of new and experimental medical technologies is from advanced western nations where significant and path breaking biomedical innovation has spanned centuries. From the 1980s and 1990s, the world's physical and intellectual boundaries became increasingly blurred as technologies, people and knowledge were accessed more easily and markets became more porous. In the context of these global changes, new areas were

explored by academics the world over, and so the literature on biomedical innovation in the West begins to intersect with other regions, taking cognisance of the interconnectedness of developments in biotechnology, trade, healthcare, scientific research and development. The scholarship collated in this chapter helps situate the study within global and local contexts of the key arguments being made. It provides a conceptual understanding of normalisation and makes a cogent statement about the normalisation process whereby social and technical worlds collide and are also enabled and affected by national priorities, global developments and new markets. There is still the need, however, for a greater body of social science research on the use of new or experimental medical treatments, devices and procedures specific to India. The findings of this study, I hope will enhance, deepen, and simultaneously broaden existing social science perspectives on stem cell experimentation in the country. While Bharadwaj and Prasad focused on international visitors at Shroff's clinic and Patra and Sleeboom-Faulkner emphasised the role of networks in provision, this study examines the embedding of unproven stem cell treatments in everyday living and in routine clinical practice across the country. It also includes the opinions of basic scientists, not found in other research on the area in India, thereby expanding the subjects of study, the scope of discussion and the landscape, quite literally.

From the writings of Franklin and Thompson we know that the decisions people made to undergo medical and/or personal risks were not necessarily obvious or simple. The writings of Bharadwaj and Prasad, although primarily focused on a single site, revealed important insights about subject formation. Narratives of suffering, grief, understanding, hope, desire, resolve and ambition are at the core of the story this thesis tells. The experiences of patients or caregivers were inspirational for the study, to say the least, and also served as important reminders to keep in constant check my motivations as a researcher in relation to their ordeals and future hopes. The emphasis by Bharadwaj on the empowering experiences of Dr. Shroff's patients, I believe, posed ethical challenges to research of this kind, where the researcher must constantly balance his or her needs with the best interests of the subject and also with the field at large. Research dilemmas such as these, discussed further in the following section, also made me aware of the dangers in the research process that could tilt the balance of power or blame towards individuals as opposed to the larger issues at stake. Importantly then, the study attempts to directly connect the micro-intricacies of the normalisation process with macro level realities, a task that current literature on India does not adequately address.

The following section describes the study's research methods, the kind of research questions asked, the study design and the research tools used to collect data. It also includes the challenges that the researcher encountered in the course of the research. The section starts with a brief background on stem cell practices in India and the history of stem cell research in order to reiterate and re-emphasise the complex and intricate nature of medical experimentation that, therefore, also demanded asking equally complicated and nuanced research questions, beyond the issue of unregulated versus regulated medical practice per se.

II. Research Methods

1. Research questions and study design

Current literature on stem cell experimentation in India is limited, yet also sufficient to know that unproven stem cell treatments were not uncommon in India's health system. Patra and Sleeboom-Faulkner's findings of public and private hospitals offering experimental adult stem cell treatments through local and global networks and the writing on the internationally maligned but also popular, Dr. Geeta Shroff, was reason and background enough for further study. Shroff's blatant publicity of stem cell treatments, a growing industry in CB banking in India, and the public and private networks through which stem cell patients were recruited, made obvious that the state's measures for institutional oversight in medical experimentation, even in its own institutions, were perfunctory at best. In 2005, the All India Institute of Medical Sciences (AIIMS) was reported in the media to have had some success using bone marrow stem cells on cardiac patients. Scientists and clinicians rebuked the study's investigators for surpassing scientific protocols and for not having published their findings in journals of scientific repute (Jayaraman 2005; Pandya 2008). Dr. Muthuswamy, the senior deputy director general of the ICMR at the time, responded to the incident:

> 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? (Pandya 2008:16)

The DBT and ICMR's guidelines on stem cell research and therapy had obviously made little difference to the medical professionals at AIIMS. According to Patra and Sleeboom-Faulkner, there were ambiguities in the document that providers were

using to their advantage. For instance, the use of bone marrow stem cells or "Bone Marrow Transplantation" was permissible according to the 2007 guidelines, "for accepted indications" (DBT and ICMR, GOI, 2007:11). The guidelines, however, failed to list these conditions, leaving the term open to interpretation (Patra and Sleeboom-Faulkner 2009). Regardless of unclear definitions, these ethical loopholes that were corrected in the latest version[7] hold little sway over irregularities in clinical research or treatment, as compliance with national guidelines is currently not legally mandatory (ICMR and DBT, GOI 2017). The provision of experimental stem cell treatments while easily argued as another example of medical malpractice in India's unregulated and highly privatised health system, is more complex a phenomenon than regulations can find solutions for. These treatments were also permitted and provided within regulated frameworks. This is complicated further by the regularised and globally accepted practice of clinicians offering unproven treatments to patients when all other medical options are exhausted. The Helsinki declaration of the World Medical Association (WMA), the internationally renowned ethical guideline for medical professionals, explicitly supports this practice. It says:

> …the physician, after seeking expert advice, with informed consent from the patient…may use an unproven intervention if in the physicians judgment it offers hope of saving life…or alleviating suffering (WMA 2013 para.37)

In addition to individual cases, highly experimental interventions administered to groups of terminal ill patients are also considered ethically permissible. As Valenstein remarked, clinicians take chances for several reasons, and the history of the only established or regularised form of stem cell treatment bears testimony to this truism in medical practice. The first clinical trial using the hematopoietic (or blood forming) stem cell (HSC) was conducted in 1957 on blood cancer patients, without any "predated knowledge of the identity of the HSC…and of the mechanism by which the bone marrow exerted its therapeutic effects" (Thomas *et al* 1957 cited in Martin, Brown and Kraft 2008:32). The clinicians, in other words, did not follow normal procedures and wait for basic science to give them the go-ahead before conducting experiments on human beings. Nevertheless, they took medical risks that ultimately made a significant contribution to stem cell treatments (Martin, Brown and Kraft

[7] The 2017 "national guidelines for stem cell research" in an annexure provides a "list of approved indications for HSCT" or haematopoietic (blood forming) stem cell transplantation (ICMR and DBT, GOI 2017:4). These indications include leukemia, Hodgkin's Lymphoma, Thalassemia, anemia etc. (ICMR and DBT, GOI 2017:63-65).

2008). According to Martin and others, “it is important to remember” that such occurrences took place in “niche areas of clinical research and activity”, limited to small numbers of patients and were, thus, a departure from the current widespread provision of unproven stem cell treatments (Martin, Brown and Kraft 2008:32). Others like Murdoch and Scott (discussed earlier in this chapter) argued that many providers functioned within these grey areas and Waldby has questioned if medical experimentation is increasingly becoming a form of medical care (Waldby 2012).

Regulations established to oversee the conduct of researchers, and professional codes among medical practitioners can further complicate vaguely defined boundaries between medicine’s objective to cure and the limits set by medicine and the human body itself. Asking questions that fall into neat moral or regulatory categories would therefore be limiting for the subject of stem cell treatment practices and for the overall issues at stake. The existing scholarship on experimental stem cell practices in India described how unproven treatments are provided in clinics and hospitals. This provision co-existed with a biotech industry, cutting edge, public research institutions in stem cell biology, regulatory and bioethical authorities and a clinical trial industry. How have experimental stem cell treatment practices occurred in mainstream medicine when scientists in India and the world over have demonstrated that stem cells are not yet ready to be used in fully-fledged medical treatments? Who were the actors and what were the activities involved in the promotion and provision of experimental stem cell treatments in India? What were the motivations and preoccupations of providers and users in the context of the unproven medical technology? How were they introduced to stem cell science and what did it mean to them in the overall framework of their personal or professional lives? Was it possible to connect all the dots, making links between the actors, including the state, and their activities, in order to develop a coherent picture of stem cell research and experimentation in the country? These were some of the questions that motivated the research to begin with and were also developed further in the course of the study and its analysis.

For answers to questions like the ones mentioned above, a qualitative study was planned with an exploratory research design. As the term suggests, the intention of qualitative research was to gain descriptive and analytical insight from the data collected without necessarily aiming for a precise or exact picture in the end (Majumdar 2005). In this kind of study, the researcher attempts to map different points of activity, events and experience of the phenomenon under study using

research tools that leave enough room for unexpected developments or unknown actors not initially planned for in the research design. An exploratory research design therefore proves beneficial for social science investigations in fields that are still evolving like stem cell research and experimentation. As information on stem cell research and treatment emerged from the laboratory or an experimental site, the media, the public, medicine, industry and state, reacted in various ways making society's engagement with stem cells both dynamic and uncertain. Dr. Geeta Shroff's practice, for instance, has continued while this thesis was written, and perhaps so did other stem cell practices, in both regulated and unregulated spheres. All of these occurred while the ICMR has persisted in improving and refining its guidelines with the most recent version published in October 2017.

2. Gathering primary data: the semi-structured interview and other methods

The total interview sample comprised 67 individual interviews and 1 group discussion with six scientists. The individual interviews included those with 33 patients and/or caregivers, 17 scientists across public and private sectors, 13 private providers that included 12 private sector medical professionals and one patient organisation Director, and four policy makers.

The main qualitative research tool used in this study to gather primary data was the semi-structured interview. Four categories of major stakeholders were selected for the interviews. These were scientists, providers, patients and/or caregivers, and policy makers. The main inclusion criterion for the study was the individual's association with experimental—regulated or unregulated—stem cell treatment, as opposed to established or conventional stem cell treatment. Patients and/or caregivers were those individuals that had already experienced an experimental stem cell treatment—in a clinical trial, a pilot study, or as treatment received on an individual basis for a price—or were in the process of receiving it. The clinicians included those practitioners charging for the unproven treatment, and or, those conducting clinical research using stem cells. In the course of the study, a patient organisation that was offering stem cell treatments was also included in the provider category. In addition, non-practicing medical professionals that currently held management positions of stem cell related facilities in institutions offering treatments were also included in the category of the provider. These medical practitioners who were not directly involved in providing experimental stem cell treatments were encountered during data collection and were not initially included—as was the patient

organisation—in the category of stem cell provider. In the case of scientists, any individual involved with human stem cells or using animal models in stem cell research was listed as a potential respondent. As far as policy makers were concerned, government officials and or any individual currently or formerly associated with relevant state departments or regulatory bodies were among those listed as sources for primary data.

For each category, a separate interview schedule was designed. The interview's main objective was to gain an in-depth understanding of the respondent's personal encounter with stem cell treatments. The open-ended format of the semi-structured interview functioned as a guide to help steer the discussion in a particular direction, while at the same time it also encouraged free-flowing conversation. In the case of patients or caregivers, for instance, questions were asked about the patient's condition, the journey from initial diagnosis to the individual's and or family's encounter with stem cell treatment, information on the stem cell provider, the decision making process including family support, details of the procedure, expectations and perceived outcomes of the treatment, perceived risks and fears around the treatment, challenges faced in the past and the present by the family and or individual, reflection on past decisions and plans for the future. The questions, thus, intended in "giving voice" to an individual's feelings, motivations, hardships, joys, losses, desires, fears and hope, for a life lived with the realities of a debilitating and incurable condition (Hammersley 2006:9).

Patients or caregivers who had tried stem cell treatments were expected to be those people who had " 'already' " experienced feelings of disempowerment due to "their illness' " or that of a loved one (Low 2013:88 cited in Alaszewski and Wilkinson 2015:177). A semi-structured interview lent itself—more than structured formats—to the creation of a sensitive environment for an individual to recount difficult memories and cope with emotions that could unexpectedly be invoked by the discussion. The interview's flexible structure, which is its main feature, also made space for nuance and ambiguities that may have arisen in people's responses to a subject mired in controversy and uncertainty. Questions asked to providers and scientists also delved into "their distinctive biographical experiences" in addition to their views on stem cell science, its clinical future, and specifics of their own practice and or position on unproven treatment provision (Hammersley 2006:9). The personal narrative was, therefore, not only sought from patients and/or caregivers but it was also considered

important to have an insight into the private thoughts, motivations and interests of other categories of respondents.

The semi-structured interview is a data collection method common in ethnographic studies, the other methods being participant and direct observation. As the terms suggest, in participant observation, the researcher interacts with the respondent's environment or participates in an activity while in the direct observation method, the researcher is only an observer of the activity or environment. Since ethnographic research "emphasises the importance of studying *at first hand* what people do and say in particular contexts", these research tools usually require "contact" with participants for extended periods of time (Hammersley 2006:4). The sensitive, highly networked and usually unregulated nature of stem cell provision, made pure ethnography of patient-doctor encounters and other stem cell practices at a clinical or non-clinical site difficult[8]. In the case of patients and/or caregivers interviewed, observing them in their daily life had been possible to a limited extent. Of the 33 patients and/or caregivers in the sample, 14 were interviewed in their homes and three sets of parents were interviewed in their child's special education school. In addition, four patients who had been participants in a research study were interviewed at the hospital during follow-up check ups[9]. In these settings it was possible for the researcher to engage with the respondent's child or family member and also directly observe, for example, how caregivers interacted with special needs children who had undergone stem cell treatments or how adult patients with various debilitating conditions negotiated the physical and emotional demands made of them in the clinical space or at home. Interviewing these individuals for extended periods, however, had its challenges. For example, in the case of spinal injury patients interviewed at the hospital, the follow-up tests, medical personnel or other needs of the patient had interrupted conversations. In another instance, interviewing families coping with MD had required an interpreter that disrupted the flow of conversation. Moreover, the children were present during the interview but it was unclear whether they had any understanding of the issues being discussed or of the activity around them. The presence of the boys, aged 19-20, as silent observers was, thus, cause for hesitation on the researcher's part to ask family members certain questions.

[8] Bharadwaj's and Prasad's easy access to Shroff's stem cell practice appears to be an anomaly in the context of unregulated treatments. Shroff, in having allowed these internationally based scholars to closely observe the workings of her clinic, it could be argued, had done so in the same vein as her consistent public defiance of her critics in India and abroad.

[9] Permission to interview patients at the hospital was obtained from the institution's ethics committee

With the exception of three patients/caregivers for which the interview was sent via email and/or post, the other interviews from all categories were held face-to-face. Among the face-to-face interviews across all categories, three were done via Skype on camera, and the rest were held in person in locations such as the person's home, child's school, hospital or clinical site and in one case, a guesthouse. With the exception of two respondents—one clinician and one scientist—who did not permit the researcher to tape record the interview, all other interviews were recorded with the respondent's permission. Prior to the interview, the background of the study was discussed and the respondent was given an informed consent form followed by some time to ask the researcher any questions regarding the study. The consent form contained the key requirements, among others, of interviewee autonomy and confidentiality. The identities of institutions, hospitals or any other entity discussed during the interview have also been protected. In those instances where the interview did not take place in person, the consent form was sent via email or post before the interview took place. The forms were translated into Hindi and later when the need arose there was also a version in Tamil. The consent forms and schedules for each category were included in the research proposal that underwent an ethics review by the JNU institutional ethics review board.

Information gathered through interviews and observations was supplemented and contextualised by other primary and secondary data on stem cell research and experimentation collected during workshops and seminars, field notes, informal discussions with special educators or disability specialists, a review of government and industry reports and policy documents, peer reviewed literature, the print media and the Internet. Three respondents also provided the researcher with documents such as a consent form of a pilot study or other documents they had to sign prior to the treatment as well as the doctor's prescription for stem cell treatment.

3. Identifying the study's respondents

Identifying patients, caregivers and providers willing to be interviewed, given the subject's personally sensitive and potentially controversial nature, was a major challenge of the research process. On-line searches, personal contacts, attending seminars or conferences and the respondents themselves were major sources for identifying interviewees. Wherever possible, emails were sent to each prospective interviewee explaining the intents and purposes of the study along with a letter from the PhD guide. Among the total sample, locating and interviewing scientists was the

least problematic of all the categories. Most public research institutes have online information on the kind of research conducted and the contact details of the scientists and departments. Moreover, with scientists, regardless of private or public affiliation, the interview was less likely to raise issues of sensitivity than with other categories. For all categories, including scientists in the private sector, the snowballing and purposive sampling method of qualitative research proved useful. As the terms imply, these methods meant that the researcher deliberately sought people, situations and or Internet searches that would most likely lead to potential participants. Initial contacts found online, at events or through personal connections resulted in interviews with them and or leading to information on other respondents. For instance, a caregiver was the source of contact details of another parent, both sharing the same stem cell provider. In another instance, a spine surgeon who had conducted a clinical research study using stem cells was identified as a potential study participant at a public consultation on guidelines for stem cell research organised by a state body. Later, an email communication with the clinician explaining the intents and purposes of the study resulted in an interview with him at the hospital where he practiced. This association with the clinician also led to interviews with four of his patients with spinal cord injury who had participated in the stem cell study. These individuals were also interviewed at the hospital when they returned for follow-up check ups. With regard to the independent practitioners, an on-line search was the main source of information. Google searches used words such as “stem cell clinics in Delhi” and “stem cell clinics India”. Two practitioners had websites carrying detailed descriptions of their stem cell practice and the conditions they treated. It was evident from their websites that neurodevelopmental disorders like autism and cerebral palsy were commonly targeted for experimental stem cell provision. Personal connections with senior professionals in the field of disability led to identifying several caregivers whose children had been treated with stem cells. With regard to patient organisations associated with neurodevelopmental and neurodegenerative conditions, a random search on the Internet resulted in identifying a society for motor neuron disease (MND) and another for MS. Telephone and email communication with one of the MS society’s administrators resulted in an introduction with four of the society’s members who had undergone stem cell treatment. In the case of another patient organisation for MD, the first contact with its Director was at a meeting on regenerative medicine in the summer of 2014. Later that year, the Director introduced me to three families and was an interviewee himself.

Anticipating difficulty in accessing respondents and the need to fulfill the study's objective of widening the scope of existing knowledge, the research location was left open. Travel to interview participants or to conduct a reconnaissance was done whenever feasible. The travel included attending relevant conferences such as Bangalore Bio, India's renowned global meet on biotechnology, where both the state and industry are key participants. In addition to the city of Bengaluru, Delhi and its environs that include Gurgaon, Dwarka, Noida and Ghaziabad, comprising the national capital region (NCR), nine other locations across the country—Bikaner, Chandigarh, Agra, Dehra Dun, Madurai, Theni, Kolkata, Pune and Mumbai—were visited for interviews with respondents.

4. Interview analysis

Each tape-recorded interview was transcribed, and translated wherever necessary. To ensure anonymity of respondents, pseudonyms were given to patients and caregivers and in some cases the names of children were also changed. Scientists, clinicians, policy makers, institutions or clinics have been given alphabetical designations or names. Every effort was made to avoid using any leading information that might easily reveal the identity of an entity that was associated with the study or a respondent. In some instances, the title of a conference or the source of a respondent or institution was altered slightly or omitted entirely.

After the interviews were transcribed, the data was closely and repeatedly examined for any dominant themes and patterns in each category and across categories. From a first read of the interviews, the overarching finding of normalisation of experimental stem cell treatments was evident. Following this initial examination of data, simple codes were created for each category to organise the information from each interview into separate themes that captured the essence of the experience, situation, event, activity or opinion (Saldana 2008). For example, the codes for the patient or caregiver interviews included 'condition', 'stem cell source', 'procedure and year of treatment', 'reasons for doing it', 'perceived outcome', 'cost', 'identifying doctor/clinic' 'what the doctor said' and 'hope'. The information organised under these codes assisted in identifying several common patterns or themes within each category and in some cases between them. These patterns formed the basis of the normalisation pathways through which stem cell treatments were becoming routine. Discussed in the next two chapters, the pathways included professional and personal networks, simplicity of the procedure and other themes that emerged in the personal narratives of illness and stem cell treatments. Subjective experiences were also

analysed for themes that extended “beyond individual awareness” of a respondent’s encounter with stem cell treatments (Flick 2014:6). For instance, the self-blame and doubt that some caregivers experienced when the treatment failed, feelings that they perceived as outcomes entirely based on private decisions, were analysed as patterns that also emanated from existing policies and dominant ideologies.

5.The type of respondents: a brief introduction to the study’s main findings

Although the findings of this study are the focus of the next two chapters, the intent here is to provide an introduction to the study sample and the locations in which stem cell treatments were provided.

a) Scientists and policy makers

Of the 17 scientists interviewed, 13 worked in public sector research institutions and one at a public sector teaching/research hospital. This was not a surprising find as scientific research in India is largely conducted in state funded institutions. Among the three private sector scientists, two were associated with private hospitals and one of them held a senior position in a private educational institute for regenerative medicine. The institutions of both private and public sectors were located in Delhi, Pune, Gurgaon and Bengaluru.

The majority of scientists conducted different kinds of basic research, from using mouse models to studying the regenerative capacity of the skin, to working with a range of stem cells from the human body. These included hESC cells and the induced pluripotent cell or the iPS cell (see introduction). A laboratory also worked on human neuronal stem cells in order to investigate the cellular and molecular basis for neurodevelopmental conditions like autism.

Some of the scientists had also been members of state regulatory bodies or state appointed committees that were established with the specific purpose of overseeing stem cell practices in the country. While these individuals were placed in the ‘scientist’ category of this study, the discussions held with them also explored their role in India’s stem cell policy. In the ‘policy maker’ category there were three scientists. Among them, two were members (one former) of India’s ethical and scientific regulatory body that also oversees and assesses stem cell research in the country. The other individual was a senior scientist appointed to a special committee set up by the government to assess stem cell practices in the country and make recommendations for regulatory oversight.

b) The providers

The 13 providers of stem cell treatment included non-practicing medical professionals and a patient organisation. These respondents were based in the National Capital Region (NCR) and the cities of Agra, Dehra Dun, Pune, Bengaluru and Madurai. Four were independent practitioners and seven institutions of different kinds, such as charitable and corporate hospitals, were associated with the others including a patient organisation. While the providers interviewed were all in the private sector, the nature of provision, discussed in more detail in the next chapter, was far from homogenous.

c) Patients and/or caregivers

Among the 33 patients and/or caregivers interviewed, 11 were adult patients and the rest were caregivers. Among the 22 caregivers, ten were carers of children below 18 years at the time of the interview. In this sub-group were three couples and the rest were individual parents. The ages of caregivers and adult patients ranged from the 30's to the 60's. The ages of the children varied widely with the youngest at five years at the time of the interview and the oldest at 18 or 19.

The majority of individuals or families had travelled from their homes to other cities for the treatment. They lived in towns and cities across India with a small number residing in rural regions. The total sample represented 19 locations across eight states, Delhi and Chandigarh. These included two families from Theni district (on the outskirts of Madurai) in Tamil Nadu and a patient from the village of Baramati in Pune district, Maharashtra. The other locations included: Bikaner, Delhi, Dwarka, Chandigarh, Gurgaon, Mumbai, Pune, Nashik, Ahmedabad, Kolkata, Chidambaram, Ranikhet, Haridwar, Gorukhpur, Ghaziabad, Meerut and Agra. One family of Indian origin lived abroad and had visited New Delhi for stem cell treatment.

d) The nature of stem cell treatments, the types of conditions treated and perceived outcomes.

The earliest treatment received was in 2005, in New Delhi, at a public hospital. In the case of adult patients including those 18 to 20 years old, treatments were sought for conditions like spinal cord injury, liver cirrhosis, MS, MND, MD, orthopaedic related problems, and CP combined with MD in one instance. The children were treated for conditions such as cerebral palsy and autism.

Stem cell treatments for the majority of respondents involved the use of adult stem cells with the exception of one child who was given hECS cells for certain, and an adult patient who most likely was treated with the latter. More than half the patients were treated with autologous (the individual's own) bone marrow derived stem cells. The other kinds of stem cells used, that are included in the adult category, were cord blood and in one instance foetal or placenta stem cells were used. Not all the respondents were clear on the source of stem cells used but the majority were aware that the treatment was unusual, if not entirely sure of the meaning of experimental treatment or how it should be ethically and scientifically provided, that is free of charge and in a controlled, research environment. Autologous bone marrow stem cells were extracted from the base of the spinal cord and inserted using different methods: intrathecal or injecting a needle into the base of the spine, intra-arterial and intravenous. In the case of placental stem cell treatment, according to the caregiver, the procedure mostly involved wrapping the membrane around his son's legs, although on one occasion an incision was made in order to insert the placenta directly into the muscle. In the case of one provider, the procedure involved the in-vivo mobilisation of blood-forming stem cells in patients with liver cirrhosis. The mobilisation of cells was done by injecting a growth factor into the body over a period of a few days. While the extraction and insertion of bone marrow stem cells in certain instances happened on the same day, within a span of hours, the treatment for some patients including children involved general anesthesia, a weeks hospital stay, discomfort and pain. Some patients had negative reactions during and or after the procedure that included meningitis in one case and serious allergies in another. If these adverse responses were directly related to the stem cell treatment there was no way of knowing.

The responses of patients and/or families to outcomes of the treatment varied from very negative to doubting whether the improvement perceived was because of stem cells or other therapies, such as homeopathy, happening simultaneously, while others attributed some benefits. In two cases of liver cirrhosis, the patients had recovered, with outcomes of the treatment therefore seeming significant.

6. Ethical challenges

Creating a sensitive environment for the interviews, especially with patients and families, was not preparation enough for the ethical dilemmas that presented themselves at every encounter. Intractable and incurable illness had forced life-altering circumstances upon these individuals, some with devastating consequences.

A father had lost his daughter months before the interview. She was in her 20's and had suffered from MS. Another MS sufferer at the age of 69 was confined to a wheel chair. His mobility had degenerated progressively since his 20s when he was first diagnosed. Those with spinal cord injuries were young men paralysed waist downwards. Two families had children in the final stages of Duchene's muscular dystrophy, a genetic disorder with a life expectancy of about 24 years. These were boys in their late teens and both died some months after the interview. Every discussion involved a recounting of the painful experience of diagnosis or discovery of the condition, a reflection on the decisions made and thoughts about the future. While every respondent was aware that they could at any point move on to another question, alter the discussion, or entirely retract their decision to speak, they were, nevertheless, reminded of the emotionally stressful trajectory of cognitive and or physical impairment and for some, the impending mortality of a loved one. Some families or patients had settled into manageable routines having put the difficult past behind them. For others, the traumatic episodes were still fresh memories. There were also those who had not given up hope for cures or at least for positive improvements. A mother of an autistic child had considered trying stem cell treatment again. Another caregiver, also with an autistic child, said she would not stop searching for new treatments. In this engagement with hope, was when the ethical dilemmas of the study became most pronounced and several ethical questions became obvious. Was the researcher's mere presence in a patient's home or provider's clinic an act of giving credence to a treatment that could be plain hogwash? How could the researcher ensure to not mislead the respondent in any way and at the same time not shatter the hope that drives and sustains the minutiae of daily life with intractable illness? Was interviewing a provider who charged patients for an unproven treatment a sign of implicit support of an unethical practice?

In light of the above ethical concerns, both Bharadwaj and Prasad in arguing for a legitimate space for Shroff within the global epistemology of stem cell science perhaps placed their scholarship in a precarious position. Bharadwaj's unequivocal challenge of Shroff's critics, begs the question, if he, in the process, had inadvertently rendered his ethnography a valorisation project. Ethical dilemmas such as these were in the realm of lending more credibility to an experimental treatment than perhaps was necessary. There were also those questions that demanded a reflection on the researchers position vis-à-vis unregulated treatment. What if the researcher believed that the experimental treatment was unlikely to bring any clinical relief to the respondent or family member? In situations where the belief of the

researcher conflicted with that of the respondent, should the researcher be in any position to judge or influence the respondent's decision? Under such circumstances — of hope, desperation and vulnerability, "participation in sociological research is high-stake activity for participants" and "researchers bear a considerable responsibility to conduct themselves with care", argued sociologists, Alaszewski and Wilkinson (Alaszewski and Wilkinson 2015:174).

Difference in belief between researchers and subjects is an issue that social scientists have grappled with for a long time. "Belief" as a "problem" was analysed mostly in the realm of religion by anthropologists who traditionally studied societies outside their own (Engelke 2002:3). Ethnographers often found themselves in situations where research perspectives could potentially be skewed by either too much belief in the subject's worldview or too little. Researchers "must" therefore "strike a balance of being 'inside' and 'outside' in order to find an appropriate tone", stated anthropologist Engelke paraphrasing Geertz (Geertz 1976:223 cited in Engelke 2002:3). It was also not essential for a researcher to have evidence or proof of a phenomenon's actual existence, stated Evans-Pritchard who studied witchcraft among the Azande in the early part of the 20th century. Rather, what was important in studying the "spiritual beliefs" different from your own, was to view them as "sociological facts" that must also be understood in relation to other " 'social facts' ", he argued (Engelke 2002:5). According to Evans-Pritchard, the Azande's belief in witchcraft followed perfectly sound "logic". He found that the practice could be analysed as an "idiom for explaining misfortune", rather than " ' irrational' " superstition (Engelke 2002:5). The seemingly irrational choices of individuals and or families of this study to undergo an unknown treatment also followed a logic, that if only analsyed as acts of desperation or individual choice would not sufficiently explain the phenomenon of normalisation of an unproven treatment and neither would it do justice to the personal narratives of the individual. "If there is no attempt to understand" the subject's "point of view, the anthropologist will have failed as a researcher", said Engelke, in his discussion on the need for balance between the world of the ethnographer and that of the subject (Engelke 2002:3). Witchcraft viewed through Evans-Pritchard's "anthropological lens" had an important role to play whereby inexplicable circumstances of death or other extraordinary events were given meaning (Engelke 2002:5). In this study, so did the personal stories of respondents, including scientists, embody several and sometimes competing logics. It became increasingly clear through the process of data analysis that the pathways of stem cell normalisation in the life of the provider, patient or caregiver, must be

described as they are but they must also be viewed through a wide lens that includes the various logics and how they might fit with each other.

Those seeking stem cell treatments came from socio-economic backgrounds that allowed choice, albeit in varying degrees. Their decisions to undergo experimental treatments were acts of individual enterprise and personal struggle but each narrative we will see also bears significance beyond subjective experience. The intention of this thesis is to foreground the voices of patients, caregivers and providers and also simultaneously attempt to explain why people acted they way they did. In other words, the researcher's belief in stem cells or the technical status of stem cell research was rendered almost irrelevant in the meaning of each story, the overall patterns in the narratives and their relationship to other structural and political factors. While it was possible to reach some resolution regarding the issue of belief, the ethical conundrum around hope during data collection, however, remained. The interviews had the potential to disrupt lives that were carefully constructed around the vagaries of illness and delicately balanced between hope and despair. In these very private spaces of illness and struggle, the researcher, as Alaszewski and Wilkinson warned, needed to tread carefully.

Chapter two

Experimental Stem Cell Treatment in the Everyday World of Provider and Patient: Micro and Meso Level Pathways of Normalisation

Introduction

Sandeep was eight years old when he underwent autologous (body's own) bone marrow, stem cell treatment for cerebral palsy in a clinical trial, at a major public hospital in New Delhi. The half-hour long procedure of bone marrow removal from the spine, without anesthesia was "very painful" for him, said his parents, Mr. and Mrs. Jain[1]. The "needle…got completely twisted twice, and so they had to put it in again for the third time", the boy's father stated. Two hours later the stem cells were inserted back into the body but this time it was in Sandeep's thigh, similar to "an angiography". After the procedure the family's trauma continued. Sandeep's feet were "tied…for six hours to prevent him from moving", and so he "was crying a lot after he regained consciousness", said his father who recalled how difficult it was to keep his son still. "We had to hold him…there were about six to eight of us [in the ward], they all helped a lot in holding him" (Interviewed 17.7.2014).

The family had travelled from Mumbai for the treatment and had to spend a week in Delhi while Sandeep was in hospital. According to Mr. and Mrs. Jain, Sandeep was the 56th participant of a research study on cerebral palsy, conducted in 2006. The couple, like other caregivers, had not been faced with a choice between a clinical trial and unregulated provision but by the offer to take a chance in dire circumstances. There is currently no scientific evidence on the benefits of bone marrow for neurodevelopmental conditions. Yet, the above portrayal of stem cell treatment is a norm in the making in India's health system and not an exceptional and considered activity of medical experimentation. The intention of this chapter is to reveal how experimental stem cell treatments, of mostly adult stem cells, were being normalised in the business of everyday living and being assimilated in the country's healthcare system — public, private, regulated or unregulated.

[1] Parts of this interview were translated from Hindi.

More than half the patients of this study were treated with stem cells from their own bone marrow. In two cases of young adults with MD, the treatment was allogenic since the bone marrow was derived from the father or relatives. Bone marrow contains blood forming stem cells that give rise to only the blood lineage and therefore, until the present day, its use is clinically relevant primarily for blood-related disorders. It is important to mention, however, that experimenting with bone marrow stem cells for conditions other than blood cancers, for example, was not entirely unfounded. In the 1990s several scientific publications claimed that stem cells found in the bone marrow had potential for treating conditions other than its established clinical use. The newly discovered potential of bone marrow stem cells and adult stem cells in general was, however, short lived and the "extent to which transdifferentiation occurs is highly contested" (Martin, Brown and Kraft 2008:36). According to Scientist A from one of India's leading stem cell institutes:

> Papers...which suggested that bone marrow might transdifferentiate were very quickly refuted but there was a growth industry, of people, who were just taking cells from anywhere and putting them anywhere else in the hope that they would transdifferentiate into some other tissue but there's just no evidence at all. (Interviewed 13.4.2015)

The scientist was not arguing against taking risks in medicine. In some cases medicine "progresses" by trying "heroic situations", she said. Rather, her concern was whether clinical trials using stem cells were well "constructed" according to relevant scientific criteria, and if these studies were at all producing useful knowledge. Another stem cell scientist (Scientist E) argued how "one size fits all" does not always work in "medicine" (Interviewed 5.2.2014).

Establishing whether there was any scientific validity in the specific stem cell treatments provided in this study or if the stem cells used by medical practitioners subscribed to clinical standards or were in fact stem cells at all, lies beyond the scope of this thesis. However, presenting the current facts of stem cell research through the voice of stem cell scientists in India is considered necessary to foreground the argument of normalisation of medical experimentation in the everyday world of patient and doctor.

Using the narratives of 33 patients and/or caregivers and 13 stem cell treatment providers, I have explored how an experimental medical technology that has yet to demonstrate its safety and efficacy for clinical use was being normalised as an

almost natural and easy therapeutic choice for both provider and patient. Stem cell providers, the treatments and procedures, costs and benefits were discussed in living rooms, doctor-patient encounters, special education schools, patient organisations, professional relationships, medical-industry networks and among informal personal associations. Through various actors and their actions, their professional motives and personal reasons, the treatment was "rendered unproblematic or self-evident in the sense of seeming 'natural' " (Thompson 2005:80-81). The process of "naturalization" was an important feature of normalisation, said Thompson (Thompson 2005:80-81). The meaning of normalisation discussed in detail in the literature review, draws largely from the anthropological scholarship of Koenig, Thompson and Franklin. These authors examined the social processes by which a new or experimental medical technology becomes routinely embedded within existing and familiar clinical practices and social systems. The success of new technologies, Webster also similarly stated, "depends on whether they are regarded as making sense…within existing social relations within which they are to function" (Webster 2002:443-444). As an experimental or new technology was incorporated into known structures and practices, something different also emerged that Thompson described as "hybrid" developments, making normalisation a complex and multifaceted process (Thompson 2005:115). This study's providers, patients and/or caregivers ascribed a range of meanings to stem cell treatments. For some caregivers, the experience of using stem cells assumed a special significance that extended beyond the specifics of the treatment. In these experiential understandings, the normalisation of stem cell experimentation was similar to that of IVF's, involving technical and social processes that for its users were imbued with feelings of "ambivalence" (Franklin 1997:169; Franklin 2013). An analysis of stem cell experimentation's normalisation in society must, therefore, simultaneously include subjective experiences that make a technology a constituent of routine life but also quite separate from it. The phenomenon of a technology being normal and unusual at the same time, Franklin described as the "paradox" of normalisation, also found in the narratives of this study's respondents and becomes clearer as the discussion progresses (Franklin 2013:33).

The pathways of normalisation of experimental stem cell treatments are discussed under themes derived from interviews with clinicians, patients and/or caregivers and other primary data sources. Placing the experiences and opinions of the patient, caregiver and stem cell provider as central to the analysis, is not to ignore the dangers of subjective interpretation or in the words of Thompson to "discount reality"

—of state polices and other macro factors that have facilitated the normalisation process (Thompson 2005:33). The structural pathways of normalisation are discussed in the following chapter, while the emphasis here is to illuminate the meanings ascribed to stem cells by "different kinds of agents" for without their narratives an understanding of how medical experimentation is becoming routine would remain incomplete (Thompson 2005:33). The themes that emerged from an analysis of primary data are discussed below. Some of these categories are dense with excerpts and quotes from first-hand accounts of providers, caregivers and patients who expressed their feelings and desires, described their actions and recounted experiences with treatments, providers and sites of provision.

1. Stem cell treatment by established providers in legitimate institutions

A total of 23 establishments in ten cities, across eight states and Delhi were found to be associated with the provision of experimental stem cell treatments. These figures were derived from information given during interviews with stem cell providers, patients and/or caregivers. The number of establishments includes the actual hospital, clinic or nursing home where the treatment took place, the site of consultation as well as a few places that were rejected by patients or caregivers due to reasons like high cost of treatment. In addition to the 23 establishments, a hospital in Trichy, Tamil Nadu, providing stem cell treatment was also identified from first hand information gathered at a conference held on regenerative medicine. From interviews held with 33 patients and/or caregivers, 17 institutions/clinics/hospitals were identified in eight cities: Gurgaon, Delhi, Mumbai, Pune, Kolkata, Bengaluru, Madurai and Ahmedabad. The 13 providers interviewed that included a patient organisation were associated with 11 institutions/clinics, all of which were in the private sector. Five of these institutions/clinics were in common among providers and those associated with patients and/or caregivers. The providers were located across seven cities: Delhi, Pune, Madurai, Dehradun, Agra, Bengaluru and Gurgaon. Varying in size and type, the total number of establishments encompassed the entire gamut of institutional healthcare delivery in India. The medical professionals interviewed in the private sector were associated with: two corporate hospitals, a single specialty hospital, a tertiary care trust hospital, two charitable hospitals, nursing homes and four individual practitioner-run clinics and hospitals. From interviews with patients and/or caregivers, three tertiary care, public sector hospitals were identified. These were located in Mumbai, Delhi and Kolkata. With the exception of four families that underwent treatment in the public sector, the rest

received stem cell treatments in private institutions, making the majority of stem cell treatment provision essentially a private sector enterprise.

The sites of experimental stem cell provision were all established institutions having existed prior to the introduction of stem cell practices. Among the 13 providers interviewed, 12 were medical professionals, of which ten were practicing clinicians and the other two held managerial positions of clinical research facilities that included stem cell processing and treatments. Among the medical professionals, a few could be called clinician-researchers as they conducted research studies while also treating patients with some having PhDs in medicine. Among the practicing clinicians, there was an orthopedic surgeon who practiced at his own establishment, a liver specialist and a paediatric haematologist at a trust hospital, a diabetes consultant and a vascular surgeon both associated with charitable hospitals, another vascular surgeon practiced at a corporate entity, a spine surgeon from a single-specialty hospital, a medical professional who owned a centre for disability, and a non-medical director of a patient organisation for muscular dystrophy. To elaborate further, the orthopedic surgeon, Dr. A, for example, was an independent practitioner who had a MBBS degree from one of Delhi's most prestigious medical colleges. He owned an orthopedic hospital "registered" with the Delhi government, that he described as a "fully fledged" specialty facility (Interviewed 25.1.2013). With regard to the patient organisation, the Director had educated himself on the various aspects of muscular dystrophy after his son had died from the incurable condition. Another independent provider, Dr. B, was the director of an institute for children with disability in Delhi, and Dr. E who practiced independently in a major city in Uttar Pradesh was also a senior member of its Indian Medical Association (IMA).

In all the independently run establishments such as Dr. A's hospital, the experimental stem cell treatment was integrated into the repertoire of paid for services. Dr. A was among the four independent practitioners that provided unregulated stem cell treatments at a price. In the case of Dr. B, the stem cell treatment was offered in addition to other activities and therapies for special needs children. At the patient organisation, members were also charged for stem cell treatment that was included among other services such as gene testing, counselling and other psychosocial support offered to families coping with MD. In the face of uncertain clinical outcomes of these treatments—whether in a clinical trial or otherwise—patients were asked to continue the use of existing, primarily non-medical therapies such as physiotherapy or occupational therapy in combination with the experimental treatment. Since

conventional medicine had little to offer these individuals, the medical options were usually limited to drugs for pain relief or muscle stiffness, and surgery in some cases. Clinicians also prescribed standard diagnostic tests such as the MRI, PET or CT scan before stem cell treatments. There were about nine patients and/or caregivers who were recommended these tests for cognitive and or physical disabilities such as autism and cerebral palsy. The relevance of these tests that seemed questionable at this stage of patient history (discussed in more detail in the next chapter), added credibility to the unpredictable experimental process, according to Prasad who similarly observed the use of diagnostic tools in the provision of hESC treatment at Dr. Shroff's clinic (Prasad 2015).

Providers informed patients or caregivers about treatments in different ways. For instance, Dr. A's hospital operated an entirely covert practice via patient referrals, professional links and networks that are discussed in more detail later. There were other providers who overtly advertised their stem cell practices using the Internet. On-line information on treatments, in some instances, was disguised within the offer of clinical trial participation. In the case of the patient organisation, a workshop on stem cell treatments was organised for its members. According to the Director, about 300 families attended the event that provided participants with "the opportunity to ask every question" on MD and stem cells (Interviewed 26.11.2014). This open platform for engagement with stem cell treatments that was facilitated by the patient organisation, had given both the institution and the treatment an appearance of legitimacy, concealing the unregulated processes involved.

At the other end of the provision spectrum were research studies conducted in private and public hospitals where free[2] treatment was provided. Of the 33 patients and/or caregivers interviewed, eight received treatment in clinical trials, pilot studies or research projects. Among these patients were five adults and three children. With the exception of one adult patient, Mr. Seth with MS, who had paid to participate in a clinical trial in Israel, the rest received treatment in studies conducted in institutions in India. The other four adult patients were all young men with severely damaged spinal cords who were subjects in the same research study at a private hospital in New Delhi, specialising in spine related injuries. Among the children, two were treated in studies held in the same public hospital in New Delhi. One of them was Sandeep, mentioned at the start of the chapter, and the other was a girl with cerebral palsy and

[2] Although the treatment was free, patients had to bear costs of transport, medicines and in some cases diagnostic tests.

MD who was enrolled in the study at the age of nine. Another boy was treated at the age of 14 for cerebral palsy at a public hospital in Kolkata. In the Kolkata institution the treatment was described as a " 'project' " in " 'cord blood therapy (Stem Cell Rich)' " (Interviewed 28.3.2015). As far as the providers of the study were concerned, a vascular surgeon, for instance, at a corporate hospital was an investigator of a clinical trial for patients who were "on the verge of losing their limb" due to critical limb ischemia, a vascular disease for which stem cell treatments have proven more successful than in other conditions (Interviewed 20.11.2013).

In addition to the two broad categories of stem cell provision, of research studies and paid-for unregulated treatments, a clinician at a trust hospital had treated a child with cerebral palsy, free of charge, on "compassionate grounds" with permission from the hospital's ethics committee. The concerned clinician had explored the literature on the subject and even though he was aware of the "sketchy" data on this kind of medical intervention, he justified the experiment by describing it as a "one-off case", and covering some ethical ground by warning "the family [that] we are not very sure that this treatment will be successful" (Interviewed 22.10.2013).

2. Existing clinician networks in non-descript sites of provision

The range of medical establishments providing or facilitating experimental stem cell treatments in India indicated the extent to which medical experimentation was embedded within the health system. According to Patra and Sleeboom-Faulkner, "it is quite a daunting task to record how many centres or hospitals in India provide stem cell therapy as a regular medical practice" (Patra and Sleeboom-Faulkner 2009:156). Experimental stem cell provision took place through circuitous and clandestine routes that cut across public and private sectors, local, state and national boundaries. Dr. A, for example, preferred word-of-mouth communication for stem cell treatments at his independently run orthopedic facility. The clinician didn't "think it is something to be, you know, sold so openly" (Interviewed 25.1.2013). His hospital was like any other multi-storied building, situated cheek by jowl with commercial establishments on a busy main street in South Delhi. Stem cell treatments were provided here in the form of autologous bone marrow stem cells. They were offered to adults with conditions like spinal cord injuries or children with cognitive and/or physical disability such as cerebral palsy. Some of these children were referred to Dr. A from a centre for children with disability located down the road from his orthopedic hospital. The centre was an inconspicuous, hole-in-the wall facility that functioned

from a basement on a side street. It had a website that mentioned the orthopedic hospital as a "consultancy centre" (Last viewed 9.1.2013).

Dr. A was the only independent practitioner among the four interviewed who kept his association with stem cells completely under the radar. The reception area of Dr. A's hospital had no telling signs of experimental stem cell treatments. It appeared to be a one-man show with a receptionist-cum nurse who was also the doctor's main assistant. The relatively smaller providers or "clinics" providing experimental treatments have certain distinct features, according to Patra and Sleeboom Faulkner. They are usually individually driven and network based, and the stem cell provision "revolves around a key figure or an influential individual physician who has a wider network across local, national and global levels" (Patra and Sleeboom Faulkner 2009:156). Dr. B who appeared to be more widely known than Dr. A for his stem cell practice, had mentioned stem cell treatments on his organisation's website under the guise of conducting research studies that followed international ethical guidelines and other standard protocols (Last viewed 26.9.2014). The director of an institute for children with disability, Dr. B did not provide stem cell treatments on his own premises but instead sent his patients to other medical establishments in the city for stem cell treatment. The procedure was "done in hospitals, we have got relationships, there are hospitals that I visit", the clinician stated (Interviewed 15.1.2013). Dr. B was referring to nursing homes where he practiced "as a consultant in internal medicine", describing them as "standard, homely nursing homes with all the facilities that are necessary for a sterile, clean OT" (Interviewed 15.1.2013). Although the procedure was done directly under his "supervision", the family paid the nursing homes directly, stated Dr. B. His centre only acted as a "screening authority", he said: "because we can't do it here, this is a NGO. This is a therapy centre. We have no business to be doing that" (Interviewed 15.1.2013). According to Dr. B's assistant, it was not possible to reveal any information on the nursing homes "because they have a non-disclosure agreement" with these establishments, she claimed (Interviewed 15.1.2013). Dr. B's institute can be described as a 'stem cell regional hub' in the New Delhi area for treating children with disability. He was the stem cell provider for three caregivers of this study. These parents had autistic children, one of whom (Seema) had travelled from Bikaner in the nearby state of Rajasthan, and the other from Chandigarh (Divya) for the treatment. Similarly, another independent practitioner Dr. C's hospital in Pune appeared to be the centre for stem cell treatments in the western region. For example, two patients visited Dr. C from other parts of Maharashtra and another caregiver had travelled from Ahmedabad.

Medical practitioners in public sector hospitals were not exempt from these networks of provision and therefore cannot be excluded from the dubious practice of experimental or unproven stem cell treatments. For example, a clinician in Mumbai with a successful private practice in stem cell treatments had referred the child of a caregiver to a public hospital where he did the stem cell procedure at a lower rate than what he charged privately. This clinician was a specialist in neurology and held a senior position in the public hospital.

The nature of stem cell practices described here make evident that paid-for stem cell provision was invisibly situated within existing professional arrangements in established organisations and within their legitimate activities.

3. New medical-industry networks

"New technologies" can "emerge in the context of mundane and unremarkable networks of established actors" but they can also, "on the other hand" create "their own amenable and fertile associations", stated Brown and Michael (Brown and Michael 2003:14). In some cases, networks emerged among entities such as laboratories and biotech firms that had arisen specifically in the context of stems cells or cellular technologies. In the case of Dr. A, the industry played a crucial role in his initiation into experimental stem cell technologies. Several laboratories in cities like Delhi, Pune and Gurgaon "started approaching us" he said. "When they arrived in India" they identified "whosoever is working in a particular field like deformities, cerebral palsy and all these" (Interviewed 20.9.2013).

Dr. A explained further how the system worked:

> We tie up with…probably…half a dozen…labs, so we talk to the patient, patient agrees for the treatment, we fix up a date, then we inform the lab…so they come up with all their machines and all their people with appropriate kits…so they help me…I take out the bone marrow they process it and then we infuse the bone marrow back that is how it is being done. (Interviewed 25.1.2013)

The growing popularity of CB banks, in Dr. A's opinion, was the reason for the development of an industry in cell storage and processing that offered services for cell-based therapies across India. Cord blood banks that overtly advertised their services and costs also functioned in these covert stem cell networks. Dr. B practicing in Delhi, for example, had treated Seema's eight-year-old autistic daughter

with her younger son's cord blood. Seema from Bikaner had stored the cord blood in a well-known Delhi based bank that sent the stem cell infusion directly to Dr. B when it was needed a year later. According to Seema[3], the CB bank had sent an "agent" to the hospital in Bikaner to collect "the cord cells and everything" (Interviewed 26.9.2013).

The medicine-industry nexus that was prevalent in the stem cell practices of independent practitioners also existed in larger hospitals. Rather than seeking institutional collaborations, a laboratory in one instance had sought a one-to-one relationship with a clinician practicing within a particular institution. This was Dr. D, a diabetes specialist who was associated with a charitable hospital in Dehradun and like Dr. A, had been first "contacted" by the industry (Interviewed 6.6.2014). In the case of Dr. D, the private firm that offered its stem cell processing services was Global Life Sciences (name changed), owned by one of India's largest business houses based in Mumbai. According to Dr. D, it was useful to have a clinician like him in the firm's network due to the "type of research work" that captured his interest (Interviewed 6.6.2014). Dr. D also implied like Dr. A that the industry did their background research before they approached clinicians. "Generally people…find out where the facility is", he stated (Interviewed 6.6.2014).

Dr. D's partnership with Global Life Sciences involved a quick and efficient stem cell operation. The bone marrow extracted from the clinician's diabetic patients was flown to Mumbai on the very "same day" it was removed, and "within 24 hours it reaches the lab", after which, Dr. D explained:

> They grow it [stem cells] in an artificial medium and make it in injection form and after six months they send it back to us – six does of those injections and we put it inside the patients, inject it at a regular basis for six days. (Interviewed 6.6.2014)

According to Dr. D, the laboratory received payments directly from his patients. The firm's representatives would visit the clinic from time to time to make presentations to patients about stem cell treatments. An independent relationship between a laboratory—or nursing home in the case of Dr. B's practice—and patients or caregivers was encouraged in these networks. The clinicians, in cases of Dr. B and Dr. D, portrayed themselves as facilitators of stem cell treatments and as mediators between the industry and new medical alternatives for patients. These medical

[3] Parts of this interview were translated from Hindi.

practitioners claimed to have agenda's that were quite different from the industry whose interests said Dr. D, were profit and business. According to the clinician:

> We are just giving [stem cell treatment] as a facility to patients who are willing to have this type of treatment. Otherwise, they have to visit Chandigarh or Bombay or Delhi and the expenses are always high in these cities so we have a tie up with [A] lab. (Interviewed 6.6.2014).

These providers, by depicting themselves as enablers of opportunity—for new technologies—rather than instigators, seemingly excluded themselves from a transactional relationship with patients and families. The highly commercial nature of the experimental treatments and the networks at large were automatically and strategically placed in the background. In avoiding obvious signs of commerce and industry in new services, the expectations from a regular medical encounter were, thus, not disrupted by the experimental treatment and the clinician could be relied upon as a trusted advisor or facilitator of the latest technology on offer.

While the laboratory or biotech company served as a legitimate, commercial front to the otherwise regular healthcare provided at the clinical site that offered stem cell treatments, the networks also gave professional credence to the provider. Dr. D's partnership with a laboratory of some repute had enhanced his personal sense of professional status. His agreement with Global Life Sciences was conditional on the firm giving the clinician a "certificate of association" as documentary evidence of their collaboration — a demand that the firm readily obliged with (Interviewed 6.6.2014). In the case of the patient organisation, its membership with U.S. and European alliances for neuromuscular disorders was important for widening its base at home. These international networks directed patients and families, who came across them in their search for information on MD, to the patient organisation.

The patient organisation had also established a cross-state hospital network for the sole purpose of stem cell provision. Two families from Theni district, located on the border of Tamil Nadu and Kerala, were sent by the organisation for stem cell treatments to a hospital in Bengaluru in the neighbouring state of Karnataka. The organisation's Director corroborated the existence of this network but he described the affiliated institution as a "stem cell research group" and not a hospital as did the caregivers. According to the Director, the patient organisation had signed a Memorandum of Understanding with this hospital or institution, and the "partnership" had involved the joint development of stem cell treatment protocols that included cost

structures, dosage and the different methods by which stem cells could be administered into the body (Interviewed 26.11.2014).

4. Global stem cell networks and activities

Experimental stem cell treatments provided within networks of individuals, hospitals and biotech companies, also extended beyond national boundaries and systems. The large-scale, global nature of these stem cell networks that were driven by competitive business interests distinguished them from the local, regional and national networks discussed above. Several types of institutions and actors flourished within these relatively larger global associations whose activities were not always easy to trace by an outsider. New actors were introduced into the fray in addition to clinicians, patients, institutions and the industry. These were 'stem cell agents' that formed key links in a chain of actors and sites (Interviewed 23.6.2014). For example, Vivek with multiple sclerosis underwent stem cell treatment in both China and India. The treatment had been organised by an agent that Vivek described as an "intermediary" in the entire process (Interviewed 26.6.2014). A resident of Gurgaon, in the state of Haryana, Vivek had his first stem cell procedure in China in 2007, followed by a second round of treatment two years later in India. Since Vivek had been among the first patients that the agent had sent to China he was assured by the agent that "when it comes to India" the treatment would be "free for" him (Interviewed 26.6.2014). The agent "was not a doctor, he's a businessman" who "wanted to bring this treatment to India", stated Vivek (Interviewed 26.6.2014). He had agreed to help the agent in "publicising" his experience in China even though the improvement Vivek experienced after the first procedure had "within a year" returned "to the way it was" (Interviewed 26.6.2014).

On Vivek's return to India, he had meetings with several doctors in hospitals that were associated with the agent. One of the hospitals, in Gurgaon, offered stem cell treatments at a much lower price than what Vivek paid for in China. "For that reason I decided, since it's not that much, just 90,000 [rupees], go for it and its not far [hospital AA], is just here, I don't know 15-20 minutes walking distance", stated Vivek (Interviewed 26.6.2014). Hospital AA was a multispecialty hospital with a website that described its "ultra modern" infrastructure, its hotel like interiors and "world class health facilities" (Last viewed 9.9.2016). Hospitals advertising their services by confusing "luxury and comfort" with markers of quality medical care, were practices and notions that got embedded in India's health system when the sector was transformed into an investment opportunity for big business (Last viewed 14.2.2018).

The larger corporate enterprises that could better afford high-end medical technologies became symbols of India's progress and set the standards for other hospitals to aspire towards, in both image and infrastructure. Forging global partnerships for a relatively smaller private institution like hospital AA, thus, appeared to be a means of expanding business with new medical technologies as the prime targets for investment. "Stem cell therapy & regenerative medicine" was listed under "specialties" on the hospital's website (Last viewed 11.7.2014). A closer look revealed that hospital AA had a partnership with Unistem Biosciences that described itself as "a biotechnology company at the cutting edge of Regenerative Medicine" offering the "full spectrum of stem cell solutions, from research and therapy to the preservation of…umbilical cord" blood (Unistem 2015). Unistem was associated with Beike Biotechnology, a Chinese firm that claimed to be "the world's largest stem cell provider" (Beike Biotechnology 2014). According to Chen and Gottweis, Beike Biotech is "one of the most discussed companies operating in the field of untried stem cell treatments" (Chen and Gottweis 2013:194). It has associations with hospitals and research centres in several locations in China and the success of its "business/medical treatment model" has extended the company's reach beyond national boundaries (Chen and Gottweis 2013:196). Assessing the exact extent of Beike's "large stem cell enterprise" would be a challenge, stated Chen and Gottweis, and so would be an attempt to understand its institutional make-up (Chen and Gottweis 2013:196). According to Vivek, "there are five different centres in China" and the one he visited for stem cell treatment was in Guangzhou (Interviewed 26.6.2014). Whether these centres belonged specifically to Beike's stem cell operations it was difficult to ascertain. Nevertheless, the uncovering of a web of unregulated stem cell experimentation from the activities of hospital AA in Gurgaon leading to links in China indicated the dubious nature of some of these networks and the large scale, transnational operations that were involved.

Other types of international networks were not quite so opaque as the one within which Vivek had received stem cell treatment. These international networks functioned openly and largely within the realm of established stem cell procedures. There were, however, activities incorporated within the regulated use of stem cell technologies that implied other questionable applications. For example, a corporate hospital, in Gurgaon, was partnered with a firm in the U.S. specialised in cell-based technologies. According to the hospital's Director of "laboratory and clinical research affairs", the stem cell facility was primarily established for clinically approved "oncology related procedures" (Interviewed 8.11.2013). It had a state-of-the-art

laboratory, adhering to standard protocols of Good Manufacturing Practices and a CB bank located on the hospital's premises. Among the stem cell related services the hospital provided was "point-of-care" treatment using a simple, centrifugal-based medical device that extracted stem cells from the bone marrow. The term 'point-of-care' implied using the medical device for bone marrow extraction at "the patient's bedside" or "within the operation theatre" (Interviewed 28.10.2013). A member of the stem cell facility's clinical team explained that within "half an hour to one hour we process the bone marrow cells, concentrate these stem cells and then its injected back to the patient" (Interviewed 28.10.2013). This type of medical device was not exclusive to larger networks but seemed to be commonly used by other practitioners or laboratories for autologous bone marrow stem cell treatments. For instance, Dr. A was paying a laboratory to bring the bone marrow separating device to his hospital. According to the corporate facility's Director, the Drugs Controller General of India had approved the medical device, but the Director's claim that the technology was used only by the hospital and its branches appeared doubtful. In a separate discussion with one of his clinical team members, it became evident that the device was taken to another smaller private hospital in the area for stem cell procedures. It was not possible to investigate further whether the device was used for established indications, regulated clinical trials or unregulated provision of bone marrow stem cell treatments. However, what was clear from these discussions was the existence of possibly ambiguous stem cell associations buried within legitimate international and national networks, whose activities might have blurred the boundaries between unethical and regulatory practices.

These global networks and partnerships that involved hospitals of different capacities, also operated on a significantly smaller scale, steered by the individual enterprise of the independent private practitioner. Dr. E, for example, eager to expand his practice in stem cell treatment had planned to use his connections outside India. According to the clinician, the first and essential step for a successful venture was establishing ones own stem cell laboratory in order to reduce the high costs of stem cell research. A doctorate in medicine from the Ukraine, the clinician spoke fluent Russian and had connections in Russia, the Ukraine and Germany, who were willing to provide the technical expertise for his stem cell laboratory. In 2010, Dr. E used his foreign connections to send a family friend suffering from liver cirrhosis in India for stem cell treatment in Moscow. The treatment was successful according to Dr. E and was provided at a subsidised rate for his friend whose only option was a liver transplant that the family was unable to afford. The friend's recovery was an emotional

experience for the clinician that led to his own induction in stem cells with the help of people he knew in Moscow.

5. The private practitioner: motive beyond profit

Dr. A, the orthopedic surgeon who provided stem cell treatments primarily though word-of-mouth referrals, boasted about his practice:

> The kind of stuff you've seen [patient video testimonies], it is not even ten percent of what we have done…so if we start doing this [advertising stem cells]…you could put the world on fire. (Interviewed 20.9.2013)

In Dr. A's statement was the recognition of his own power as a provider of stem cell treatments. Patients or caregivers invested great authority in the medical profession offering stem cell treatments — their only source of hope for a cure, improvement or survival. Martina, the mother of a child with cerebral palsy, had bestowed on her stem cell provider the status of a divine messenger. "Its like god has sent you to us – to…people who have this type of children", she told her doctor (Interviewed 17.7.2014). In the case of another stem cell provider in Pune, his association with divine power was self-proclaimed. The clinician stated defiantly that he had a "direct connection to God" when caregiver Karan and other family members confronted the doctor for his apathy towards Karan's father (with MND), who had waited at the clinic all day for the doctor to appear despite an appointment. The clinician eventually refused the family treatment after being "questioned" for his attitude towards the sick patient (Interviewed 26.7.2014). Dr. C, also in Pune, eventually treated Karan's father but the family had a "bad experience" there as well. Karan's father, now deceased, experienced severe complications after the treatment and never fully recovered from them. "Doctors claim the sky but that is not the case", said Karan when looking back on his father's suffering (Interviewed 26.7.2014).

Weber's understanding of "charismatic authority" provides a useful perspective within which to examine patient-doctor encounters such as the ones described above (Schnepel 1987:32). Engagements with healthcare providers still persist within traditional frameworks of power even though the Internet and other media have tilted the equation in favour of the more aware and knowledgeable patient. According to Weber, conditions of "despair and hope" or simply "enthusiasm" underlie the "complete personal devotion" of subjects towards the "charismatic authority", who in this case was the treatment provider (Schnepel 1987:32-33). The "extraordinary

qualities" that the "charismatic authority" was believed to possess did not, however, go unchallenged as the individual had to prove his powers, "originally always a miracle" and only then, in the analysis of Weber, did the authority receive validation (Schnepel 1987:33). Having charismatic authority was, thus, an unstable characteristic that could be undermined at any point in time, argued Weber. In Dr. A's hubris for instance, there was also fear of the repercussions of using an unproven treatment with unknown outcomes. After injecting bone marrow stem cells in a patient with a cyst on his spinal cord, the clinician admitted to having a "couple of sleepless nights" (Interviewed 20.9.2013). His clinical decision had been based on information "not in the literature" but rather on "what do you call that – intuition", he said with a nervous laugh (Interviewed 20.9.2013). For the stem cell procedure, Dr. A had hazarded a guess of about 100 million cells per dose or per 'stem cell injection', with some adjustments for age and body weight. This procedure is "not developed like a drug system" so "people all over the world have been trying different kinds of cell counts", he explained (Interviewed 25.1.2013).

The motivations of stem cell providers were not unlike those mentioned by Valenstein in his analysis of physicians who performed prefrontal lobotomy for almost two decades until it finally disappeared as a practice. Professional hubris, self-promotion and competitiveness were some of the personality traits of neurosurgeons that Valenstein described as major drivers in their promotion of an invasive brain procedure based on flimsy scientific grounds. However, if "questioned at the time", these physicians would have claimed the "noblest" of intentions - of relieving their patients from immense "suffering", stated Valenstein (Valenstein 1986:295). Dr. D, for instance, did not think there was anything wrong in prescribing unproven stem cell treatments for his diabetic patients. According to the clinician, "if people are getting benefit…then" "as a medico" and diabetes specialist it was his duty he felt to "start" working with stem cells (Interviewed 6.6.2014).

Scientist A urged clinicians to show more humility, "because…medical science is currently going to…have to accept the fact that you cannot treat certain conditions", she argued (Interviewed 6.12.2013). According to the scientist, the medical profession must understand that current knowledge on bone marrow's regenerative capability "has been hard won", and it works today only in "very particular cases" (Interviewed 6.12.2013). Dr. A and Dr. D of this study would disagree—as others have before them—with opinions like that of Scientist A. "Just as desperate patients will "grasp for any therapeutic straw…so we in clinical neuroscience might initially

endorse a new technology only on its promise", explained a radiology professor at Harvard Medical School (Ackermann 1981:9 cited in Blume 1992:8).

6. Informal networks and practitioner recommendations: a function of social background, personal contacts and professional status

Caregiver Nita "discovered" in her desperate search for help with her "severely autistic son" that the stem cell provider who eventually treated her child was "a cousin of a school friend". Nita narrated how she "called this school friend and said: what do you think? Is it legitimate? Should I do it? And he, therefore, set up a meeting for me", she recalled (Interviewed 22.4.2014).

In addition to institutional and clinician networks, social connections of patients or caregivers and their formal relationships with professionals were also significant pathways by which stem cell experimentation was being embedded in the practices of daily living. Apart from media sources, patients or caregivers of this study had heard about stem cell providers and or stem cell treatments from multiple informal and professional contacts that included friends, relatives and acquaintances, former users, other patients, consulting clinicians such as pediatricians and neuro physicians, alternative medicine practitioners and other professionals.

In the case of a young mother Priti[4] from Mumbai, the "Ayurvedic doctor" who was treating her child with muscular dystrophy, had informed the family "that the only treatment is stem cell therapy. It is the *last* [option]", he said, seeming to imply that the traditional medicine he was prescribing would not produce the desired results (Interviewed 18.7.2014). The alternative medicine practitioner recommended a clinician in the city who was also the stem cell provider for a few other respondents who lived in Mumbai. This clinician's support for the benefits of experimental stem cell treatments for unproven indications was apparent from his appearances on television shows on the subject that can also be found on YouTube. Another young parent of an autistic child had heard about stem cell treatments from her daughter's neurologist and found this particular clinician with the help of her child's physiotherapist. For caregiver Seema, while a special educator had been the source of information about a particular centre, it was a pediatrician's opinion that encouraged her to consider the option of stem cells. The clinician was considering stem cell treatment for his own child who was "bed ridden" with CP. "I was encouraged you know that if doctor sahib is doing it for his child then I should go for

[4] The interview was translated from Hindi, with the exception of a few words.

it", said Seema (Interviewed 26.11.2013). In the case of Mr. and Mrs. Jain, from Mumbai, another parent whose child attended the same special education school as their son had informed them about stem cell treatment at a hospital in Delhi. This parent had heard about stem cell treatments from another friend whose child was treated with stem cells. Another caregiver, Mr. Saxena, was informed about a stem cell study at the same public hospital in Delhi that Mr. and Mrs. Jain's son was treated, after he made contact with the institution that he had identified through the mainstream media and various other informal or formal networks.

The provision of experimental stem cell treatments regardless of the kind of treatment, the nature of its regulation or the provider was, thus, a largely network-based and word-of-mouth centered provision. Studies have pointed to the greater likelihood of public acceptance of a new technology if "information" about it had been sought "from personal contacts" even though "information-seeking" was not a necessary condition for the technology's popularity (McMichael and Shipworth 2012). In the nature of these informal networks and individual relationships with professionals, social class[5] also served as an important mediator for patients or caregivers often confounded by having to make a decision about experimental treatments. The story of Sapna illustrated how class familiarity operating together with notions of professional status had successfully provoked informal networks into action, having, thus, rendered the act of "experimentality" credible, normal and possible (Petryna 2007:288).

Sapna who had arthritis narrated:

> In 2013, my husband had bypass surgery and I got talking to the wife of the patient in the room next door…about what her children do…the typical time spending thing, so she said her son is working in stem cell technology…They have been doing this stem cell therapy for all sorts of things, including baldness and her husband was injected on the skull with the serum and he started growing sporadic hair. (Interviewed 21.05.2015)

The prospect of stem cell treatment was not new to Sapna when she met the woman at the hospital. Rather, it was the nature of the encounter that had encouraged Sapna to actively think about stem cell treatments for herself. In addition to the woman's own relatives who had experimented with stem cells or made it a business,

[5] Social class is broadly understood to be "rooted in material resources (via income, education, and occupational prestige)" and corresponding subjective perceptions of rank vis-à-vis others" (Cote 2011:43).

other social affiliations worked in Sapna's favour. The owner of the stem cell firm that extracted and prepared the stem cells was a close relative of "the big famous gynaecologist Dr. [Kulkarni] from Bombay" and "so you know, that also kind of established proper authenticity", Sapna said (Interviewed 21.05.2015). Sapna was reluctant at first to experiment. She "didn't have much of a problem, in the sense" there was no experience of "pain", but determined to avoid the only medical option of surgery she had explored the possibility of stem cells (Interviewed 21.5.2015). Sapna searched the Internet for stem cell treatments, contacted her friend's daughter-in-law living in the U.S., and was encouraged by her husband's interest in the subject. Eventually, she "decided to "give it a shot" (Interviewed 21.5.2015). On the recommendation of the treating clinician, Sapna later contacted former patients. One of them was a woman who had benefited from a "booster dose" of stem cells. "So finally" after considering all the pros and cons "the whole thing was fixed", said Sapna (Interviewed 21.5.2015).

In the absence of known protocols for experimental or relatively unfamiliar medical procedures, a reliance on former patient networks and support groups by both doctors and prospective patients is not an uncommon phenomenon, stated Hanefeld and others (Hanefeld *et al* 2015). On the basis of a study on the decision making process of medical tourists, the authors found that informal networks were stronger influences in the choices of providers rather than issues of cost and "expertise" (Hanefeld *et al* 2015:356). The informal networks of these individuals comprised personal references and web based communication in addition to contacts with patient groups. Social networks, according to Tach and Cornwell, also "embed people…with a sense of belonging" and "trust in others", spurring them into action (Tach and Cornwell 2015:250). For caregiver Martina from Mumbai, a series of fortuitous social events resulted in her decision to experiment with stem cell treatment for her son with cerebral palsy. The first among these was a visit to a church in Kerala that resulted in a conversation with the preacher who mentioned the practice of stem cell treatments in Mumbai. Back home, Martina did not waste any time. She followed through with a private stem cell provider and requested her local church to fund the treatment. Martina was given the money from the church within a month of her appeal "because our church", she said: "they know my son very well and my husband works in the church so due to that…we got a quick answer" (Interviewed 17.7.2014).

To recall the work of Blume and the other authors he cited, the nature of social "networks" linked a range of actors who via "technical and social" processes of "mutual shaping" had influenced the extent to which a technology such as the x-ray got embedded in both markets and health systems (Blume 1992:58-59). For patients or caregivers of this study, learning about stem cells through familiar social interactions and settings such as the friendly wife of a patient, the involvement of relatives and acquaintances, former patients and trusted organisational structures– were all crucial elements in building a supportive atmosphere within which an uncertain medical territory could be possibly traversed. For Martina, the church was an institution that was central to her daily life. It had provided her with the means to pursue, what was seemingly the only option left for her five-year old son with cerebral palsy. The child was unable to speak, walk, or hold his head straight. In the case of Sapna, the association of a well-known doctor with the stem cell processing firm had given the experimental treatment a quickly found credibility.

Considerations of class and professional reputation that played a role in Sapna's decision-making process, also operated in the type of business associations forged by stem cell providers. For instance, Dr. A's preference to use a particular stem cell processing laboratory over others was because of its influential clientele. Like Sapna, Dr. A was of the opinion that the laboratory's association with one of India's most eminent cardiac surgeons had rendered the establishment "more authentic" (Interviewed 20.9.2013).

In the personal narratives of this study, social class that informs the entire discussion in chapter four, emerged as an integral force in the embedding of experimental stem cell treatments as it had with other new or experimental technologies. Functions of class familiarity and social connections had helped shape the nature of stem cell networks and also consolidated contacts and associations, keeping them active and relevant for old and new actors and activities.

7. The stem cell procedure: "simple" and without "harm"

> Prefrontal leucotomy [lobotomy] is a simple operation, always safe, which may prove to be an effective surgical treatment in certain cases of mental disorder. (Moniz 1937:1385)

These were the words of neurologist Egas Moniz, a major figure in the widespread practice of the experimental brain procedure. Although Moniz's claims were highly contested, the surgeon's popularity and that of prefrontal lobotomy resulted in him receiving the Nobel Peace Prize for Medicine in 1949 (Valenstein 1986).

> The stem cell "procedure is a simple injection, it is nothing very great like a heart transplant or a lung transplant…you just inject it [cells], that's it. I mean there are various ways depending on which organ you want to target but basically it's just an injection that's it (Interviewed 15.01.2013).

The above explanation of experimental adult stem cell treatments was given by Dr. B. His views were shared by other practitioners like Dr. A. who claimed that the entire stem cell procedure takes only "about 40 minutes" (Interviewed 25.01.2013). This is because:

> You're not doing anything more than an injection" and "when you extract bone marrow it is done through a needle…so even that's a puncture kind of a thing. (Interviewed 25.01.2013)

Simplicity in operating machines was one of the reasons given by Blume and others for the rapid adoption and use of new diagnostic technologies like the CT scan and the x-ray. However, the perception of ease was a double-edged sword in the process of technological diffusion. To recount the opinion of Dr. A.U. Desjardins, the increasing simplicity in managing the x-ray machine would encourage even "quacks" to use it, he warned (Desjardins 1929:1035 cited in Blume 1992:34). The x-ray's discovery had undoubtedly been revolutionary. Its use of cathode rays revealed the insides of the human body like never before, but in its application there were also risks and the chances of harm due to misuse were high.

With regard to stem cell technology, a revolution has not occurred quite yet — a fact belied by the simplicity of its application. Injecting stem cells was "so easy" that medical interns requested Dr. F, a vascular surgeon, if they could spend "two hours" with him to learn the procedure (Interviewed 3.12.2013). "What do you mean teach us stem cells?" the surgeon lamented their ignorance (Interviewed 3.12.2013). "I wish I knew" was the retort he had wanted to respond with. It is "that kind of attitude" in the medical profession that propagates unwarranted stem cell use, only made worse by "desperate patients" who "will do anything", said Dr.F (Interviewed 3.12.2013). Patients and/or caregivers were also encouraged by the deceptively

simple stem cell procedure — of extracting bone marrow and inserting it back into the body. “We thought there might be some big surgery but it was nothing like that”, said Priti, whose daughter was treated for muscular dystrophy (Interviewed 18.7.2014). Another caregiver, Mr. Saxena[6], had chosen stem cell treatment over conventional options for similar reasons:

> There are operations that claim to straighten the legs... but then we thought that if we do the operation and it goes back to being the same, there was fear in that. In this [stem cells] there was no fear that it could be reversed**.** (Interviewed 17.5.2014)

Mr. Saxena’s daughter, mentioned earlier, was treated for muscular dystrophy in a pilot study at a public hospital. “There are no risks” in the procedure, he was told by the doctors, but they also warned him that stem cells may “not work” (Interviewed17.5.2014). “We can’t give you definite results. It can be positive or it can be negative, but there will be no harm”, the doctors said (Interviewed 17.05.2015). Many providers did not guarantee a cure from adult stem cell treatment but they did assure patients and/or caregivers of the adult stem cell’s safety, relative to the potentially cancerous human embryonic stem cell. Autologous bone marrow stem cells are “your own cells so there’s no risk of any reaction or anything going worse”, explained Dr. A (Interviewed 25.1.2013). His words were echoed by a patient, Mr. Moré[7], who chose a treatment option riddled with uncertainties because he stated: “in any case” when “its my own bone marrow…what side effect can there be from it” (Interview on 6.5.2014). In responses like Mr. Moré’s, lies “the danger” stated Dr. F, who strongly believed that stem cells is “not a pseudo science” but at “the same time” “its so simple” “that all and sundry” are doing it (Society for Regenerative Medicine and Tissue Engineering (SRMTE) 2013).

Autologous cellular therapies can be “variously” described as “high-tech” requiring significant capital investment” and also “sufficiently low-tech that it can be carried out in a ‘garage’ ”, stated Kent and others (Kent *et al* 2006:7). The relative ease of bone marrow extraction and insertion added to the treatment’s appeal for both doctors and patients. The clinician was a crucial conduit of normalisation and the more structured space of the medical encounter was an important site whereby the stem cell was produced as the miracle bearer and also simultaneously within reach of ordinary, every day care. While most patients and/or caregivers consulted their social

[6] The interview was translated from Hindi, with the exception of a few words.
[7] Translated from Hindi.

networks and equipped themselves with knowledge about stem cells from the Internet and other media sources, they also relied on the doctor's fiduciary duty of care. For caregiver Nita, for example, the clinician's empathy was the beginning of a relationship based on trust. Nita recalled her first visit to the clinician with her husband:

> We asked her [clinician] a simple question that if you had a child like us would you try it [stem cells]? And she said yes, I most certainly will. She had no reason to lie to us and we felt that confidence that she was not taking us for a ride or we weren't being coerced into something. (Interviewed 24.4.2014)

The clinician was ascribed with great powers because of the mere fact that he was one, said Foucault, in his analysis of medicine's growing influence in the 19th century, in treating and managing the mentally ill (Rabinow 1984). Foucault argued that the unquestioned supremacy of the doctor over inmates of a mental asylum, rested not on the practitioner's hard earned "scientific competence" but a pre-existing belief "in the esotericism" of objective knowledge (Rabinow 1984:163). In other words, the doctor did not possess any unique skills for curing mental illness, but rather his authority had been "borrowed" from science (Rabinow1984:160). "A man of great probity, of utter virtue and scruple, who had long experience in the asylum, would" therefore "do as well", said Foucault (Rabinow 1984:159). With the growing presence of the clinician as the embodiment of scientific authority and, thus, the arbiter of mental illness, there came a point said Foucault, when seeking the source of power became irrelevant as the mere knowledge of its existence became reason enough for power to be acknowledged.

The doctor-patient relationship in Foucauldian analysis has undergone a transformation today, many argue, in contexts of new healthcare technologies and the changing relationship to disease itself. According to Rose and Novas, The patient in advanced western economies is no longer a submissive player in the healthcare system. Developments in cellular technologies, genomics and genetic research that target the individual body as the source for both cures and the pathology, are increasingly making demands on patients to harness their own biological potential and resources in order to live healthy lives. What is defined today as cutting edge biomedicine is an orientation towards the molecular body—of genetic codes, cellular messages and gene expressions, niches and environments (Rose 2007). These biotechnical advancements imply a highly individualised form of medicine that would

cater to a person's own biological make-up or small populations suffering from rare conditions. Set backs in clinical applications have not prevented positive predictions of market growth in personalised medicine that includes stem cell treatments. As 21st century medical technologies become unequivocally viewed in terms of "opportunity" for wealth and wellbeing, patients in the West, as discussed in the literature review, have also responded to these shifts in medicine on terms that are becoming their own or in partnership with authorities (Rose 2007:51).

Patients in India are also increasingly being transformed into consumers as they negotiate options in a growing healthcare market. In the case of stem cell treatments in this study, the doctor-patient interaction in certain instances also demanded active involvement from patients and/or caregivers through the course of the treatment. Majority of these individuals had entered the clinical space already informed about stem cell treatments from the Internet, the print media, social networks, treating professionals and other sources. Patient demand and the industry's outreach strategies were largely the reasons given by Dr. A for starting a stem cell practice. The clinician claimed to give patients or caregivers greater control in the decision making process about stem cell treatments. "If you are happy" with the results then "I'm happy, and if both of us feel like going through more stages" then it is possible, is what Dr. A told patients or family members after completing the first round of stem cell treatment (Interviewed 25.1.2013).

Power equations between doctor and patient might be changing in particularly private, urban health care settings that are seeing increasingly informed, paying patients. The change is, however, misleading, as the empowerment of patients and families emerges from a personal crisis that is also fed by larger structural issues—discussed in the next chapter—that may go unnoticed by individual actors. In a personal crisis, the clinician's assuring presence and assumed wisdom are qualities still expected of the medical professional who remains "Father and Judge, Family and Law" for the patient and caregiver (Rabinow 1984:160). "We act as a sort of guardian of the patient", stated Dr. B as he discussed the procedures patients underwent before and during the treatment (Interviewed 15.01.2013). For Nita, mentioned earlier, the personality of the clinician was a compelling feature of the medical encounter, regardless of the doctor's ability to cure her son. The clinician's attitude, that Nita felt was one of empathy combined with openness about the uncertainty in treatment outcomes made Nita and her husband "feel very safe" in their decision to experiment (Interviewed 24.4.2014). Nita was told that an x-ray of her son's brain after the

treatment would not show any sign of change if it did occur. “It will not be something that you can put on paper”, the clinician had said, and this “honesty and…candidness really helped in doing stem cells”, stated Nita (Interviewed 24.4.2014).

8. The clinical space

“We saw a lot of positive stories around us” said Nita, when describing the atmosphere of the clinic where her autistic son was treated with human embryonic stem cells. She met other families there who had benefited from the treatment, and like other prospective clients she was shown a film that portrayed former patients who “would write back and say they transformed their lives” after the experience (Interviewed 24.4.2014). The stories of hope that Nita heard at the clinic had reaffirmed her decision to experiment. The clinic’s encouraging ambiance had a salubrious effect on her, rendering the overall experience as not merely bearable but even enjoyable. Nita’s response to the clinical site, explored further in the following theme, agreed with Gieryn’s argument of a sense of place. It goes as follows: “A place is not a place” if it is not “interpreted, narrated, perceived, felt, understood and imagined” by “ordinary people” (Gieryn 2000:463). Imbibed with meaning, a place constitutes experience or memory and functions not as mere physical background to an activity, but can also be “an agentic player in the game”, said Gieryn (Gieryn 2000:466). In other words, the clinical site itself had the capacity to facilitate or hamper the normalisation process of experimental stem cell treatments. For women like Nita, fearful for their children’s health and desperate to find solutions, the clinical space had signaled hope and optimism for the journey ahead.

In Dr. C’s waiting room at his independently run hospital in Pune, was a video loop running through the day showing patients, including children and international patients, walking or indicating significant improvements in their various conditions after stem cell treatments. The television monitor was not very large but it occupied centre stage in the reception area where a captive audience awaited their turn in hope for a cure.

9. Experimentation as reassuring ritual

Koenig, in her ethnography on the routinisation of TPE or Therapeutic Plasma Exchange (see literature review), examined how non-technical tasks performed with every application of the new or experimental TPE were eventually incorporated by hospital staff into the set of activities that developed around the technology’s eventual routinisation. In other words, as TPE was routinised in the hospital so were

the social activities that were initially adopted to help ease the pressure of introducing a new procedure into clinical practice. The repetition of these tasks or "rituals" as Koenig described them, brought order and a sense of normalcy to the uncertainty that prevailed in the clinical setting — a common state of affairs in the application of new or experimental treatments (Koenig 1988:479-481). A similar, but tentative social order was also created when rituals developed around stem cell treatments provided caregivers with the comforting familiarity of routine and a sense of purpose in their lives. In the context of this study, the rituals had extended their purpose of order and control beyond the confines of a hospital ward or clinic. The tasks introduced stability to the unpredictability of daily living that typifies the experience of families coping with chronic conditions. Nita, for example, "didn't know what it meant for the future" as she raised her autistic child (Interviewed 22.4.2014). Nita described her son as a "violent" child who "didn't speak" and so "we were quite desperate", she said (Interviewed 22.4.2014). Her son "was very difficult" when they initially visited the clinic for stem cell treatment but later, she stated:

> I found [the doctor] did it [the treatment] in a very nice way. She ran a little school for the children, so it was two hours that you spent in the hospital and they got a phys ed class and they had a special educator who would work with speech and language with them so that was very nice. (Interviewed 22.4.2014)

Families coping with intractable conditions make "meaning for the illness situation that preserves their sense of competency and mastery", argued Crespo and others (Rolland 1985, 2003 cited in Crespo *et al* 2013:744). For Nita and her son, the stress of every day life with autism was temporarily replaced by the relative calmness of their structured days during the course of the treatment. Nita's description of her overall experience at the clinic is as follows:

> It ended up becoming like a family…and so I actually quite enjoyed the whole process [laughs] I have to say. We would go in the morning, we'd have two hours of class, then we'd get an injection and we'd go back [home]. (Interviewed 22.4.2014)

The literature on the role of ritual in circumstances of chronic conditions such as autism spectrum disorder in children, points to the important function served by rituals and "regularity of routines" (Crespo *et al* 2013:744). Positive health outcomes including improvement in mental health were found to be associated with routines and rituals that, therefore, become major "resources" for families dealing with the

"child's specific need for predictability in the household schedules" (Crespo *et al* 2013:741).

Another caregiver, Divya, was unable to ascertain whether her autistic son's relatively calm behavior in the first six months after the stem cell treatment was due to the clinical intervention or an outcome of how "organised" their lives had become during the treatment. In 2011, Divya travelled to Delhi from Chandigarh with her son and his helper for the treatment. The treatment required a month's stay in the city and so they found a guesthouse "where they lived according to a system" she said. Divya was happy with this living arrangement that gave her the freedom to control her day, quite unlike her previous experience of staying with relatives where she had no "command" over the kitchen or her time. When they returned to the guesthouse every day after the treatment, there were no "distractions" it was just the three of them, she stated. Divya's son Rohan was prone to "tantrums" but in the guesthouse he "got all my attention", she said. There were nobody's "instructions" to be followed except her own and so the overall stay had been "great". If Rohan "wanted his food he would go sit at the dining table which was such a wonderful sight", she reminisced (Interviewed 3.1.2014)[8].

Three years later, Divya was unsure whether she would try stem cell treatment again, but nevertheless she held on to the happy memory of the precious time spent with her son: "I can't really describe what that phase was but I think it helped me", she recalled (Interviewed 3.1.2014).

Rituals are social interactions or activities laden with symbolic meaning that can "only be fully interpreted by the insiders—the family members with a shared history", stated Crespo and others (Crespo *et al* 2013:731). A domain of anthropology, rituals are usually analysed in the context of religion, although a ritual is also understood to contain "both expressive and instrumental aspects simultaneously" (Bell 2009:70). Both caregivers, Nita and Divya, had ascribed a special significance to routine activities such as the clinic's procedures, special education classes or the mundane task of preparing food and mealtimes. Regularly performed activities such as these are defined as rituals not because of their unique distinction from other kinds of tasks, but rather for their practical and symbolic value that is embedded within "other forms of human action" (Bell 2009:70). According to Bell, although a ritual can possess both utilitarian and symbolic qualities it is the "expressive aspects" that are "usually

[8] Parts of the interview with Divya have been translated from Hindi.

considered to be more authentic to ritual per se than its pragmatic aspects" (Bell 2009:7071). The symbolic feature that makes an activity a ritual, both Geertz and Weber believed, is formed in the individual or collective "quest for meaning in suffering" (Seeman 2004:55). For caregivers in this study, the meaning ascribed to the routine around stem cell treatment had ultimately fulfilled a purpose that went beyond the expectations of the treatment itself. The 'stem cell rituals' had produced a cherished memory of the overall experience. In the process of being performed, these rituals had established pathways for the treatment's normalisation that were laden with multiple meanings, of a practical kind and those that simultaneously became symbols of personal resolve, strength, acceptance and kinship.

As primary caregivers of children with autism, the rituals that both Nita and Divya described during the treatment process inadvertently became highly personalised and transformative experiences that transcended other routine activities they practiced in their daily lives. These young women, in their 40's, were supported financially by their spouses and had adequate resources at their disposal to make decisions regarding the well being of their children. Yet, they were alone as they coped with emotions that oscillated between hope and despair, acceptance and personal failure, and other contradictory feelings that complex disorders like autism invariably evoke among caregivers (Crespo *et al* 2013). In the case of Nita, accepting her son's condition had been a slow and painful process. The routine of the stem cell clinic had provided her with a sense of community and the feeling, of even, happiness. For Divya, bonding with her son that was enabled through rituals established for the duration of the treatment assumed major significance in her narrative. Equally important was the function of these rituals as signs of the caregiver's recognition, in retrospect, of their own strength and resourcefulness in undertaking the traumatic step of subjecting their children to an unknown treatment. Divya's son, for instance, went through several bouts of severe vomiting soon after the bone marrow had been extracted from his spine. There was no conclusive way of knowing if the illness episode had been an adverse reaction to the procedure. Divya was full of recrimination towards herself as she recounted her story. Perhaps it was a huge "mistake" on her part, she felt, for not having investigated the providers and clinics more closely. When her son fell sick she "was alone to take decisions" and "didn't know what to do or what not to do" (Interviewed 3.1.2014). Dr. B, Divya's provider, dismissed the possibility of the child's reaction having anything to do with the stem cell procedure. After her son stabilised, Divya having come so far in her

pursuit of hope, eventually gathered the courage to continue with the stem cell infusions.

Emotions of anxiety and fear combined with hope that were present in Divya's narrative also formed a common thread in the stories of other caregivers and patients. They described their experience with stem cell treatments as a time of great hardship, but in their recounting was also a story of taking control of their illness or that of a loved one. In the context of these meanings ascribed to and implicit in ordinary activities, the stem cell ritual can also be designated as a "special type of sign" that carried the message of "profound social consequences" if experimental medical technologies become routine (Gordon George 1956:117-119). Like IVF, that Franklin described as "at once miraculous and ordinary, recognisable and unfamiliar, routine and exceptional", and thus, "a curious new norm of civilized existence", the 'stem cell ritual' also contributed to the process of the treatment becoming ordinary and easy enough to access, yet unusual and unfamiliar in how it worked or uncertain in what it would do for the people who used it (Franklin 2013:29).

The stem cell rituals described above evoked feelings of comfort, family bonding, resilience and pleasant memory. These meanings attached to rituals that were explicit and implied in the narratives of caregivers were positive facets of what rituals, and in particular this type of ritual activity brought to those who performed it. However, to understand better the hidden aspects of the normalisation process of stem cell treatments that occurred through these seemingly "ordering" activities (Jasonoff 2004:25), Brock's definition of ritual as "adaptive behaviors" to crisis proves useful (Brock 1990:285). For Brock, "crises are viewed as direct challenges to one's communal patterns of living" and rituals in the form of liturgical practices become coping mechanisms or mediators of the crisis (Brock 1990:285). Although the context that Brock speaks of is religious and ritual is understood as "formalized responses" to adversity, his analysis is relevant to stem cell rituals that played a supportive role in the face of personal chaos inextricably tied to larger macro forces—of commercialisation in healthcare, clinical research and regulations, an irresponsible media, inadequate support systems for disability and other policies that played a disruptive rather than a cohesive role in the personal narrative. Geertz, too, situated ritual practice within its "dysfunctional implications" and broader transformational tendency, rather than emphasising its "harmonizing, integrating, and psychologically supportive aspects" (Geertz 1973:143). From Geertz's observations of a ritual performed in urban Indonesia, he found that the ritual ultimately failed to fulfill its

expected and traditional role of bringing cooperation and camaraderie among neighbours of the community concerned. The reason cited by Geertz for the ritual's eventual irrelevance was social change that had occurred in the community in the aftermath of "urbanization" and "occupational differentiation" (Geertz 1973:148). These societal transformations were among other "structural changes" that had undermined the earlier "cultural homogeneity" within which the ritual would have been performed (Geertz 1973:148). The diminishing role of the ritual for the community concerned, according to Geertz, was not a manifestation of "loss" and yearning for former "ways of life" but rather the desire to construct "a new one" that began to take shape in the early decades of the 20th century (Geertz 1973:150). The meaning of rituals in culture should, thus, be interpreted rather than taken at face value, argued Geertz. In a similar vein, stem cell rituals were acts that bore implications for public policy as much as they were a personal response to crisis. From the narratives of caregivers, Nita and Divya, we know that the rituals they described, unlike the Indonesian ritual of Geertz's study, had performed their prescribed and familiar function of providing reassurance, comfort and normalcy in circumstances of vulnerability, sadness, fear and as well as hope. The enactment of hope and the feeling of despair that manifested in these ritual activities and belonged to private worlds and individual struggles, were also acts or feelings informed or misled, enabled or prevented by the conditions within which they were enacted. This association between actions and thoughts of individuals and families with broader contexts and conditions within which they were expressed or enacted will be made clearer in the chapters that follow.

Conclusion

This chapter reveals a range of actors and activities involved in making experimental stem cell treatments routinely possible. There were clinicians in private practice charging patients, a patient organisation that facilitated stem cell treatments for its members, private and public hospitals providing free treatment in research studies, biotech companies targeting individual clinicians, medical and alternative medicine practitioners encouraging caregivers to experiment, personal contacts of patients and caregivers and chance encounters that mobilised individuals and families into making decisions and choices about stem cell treatments. In the discussion on the various themes that emerged from an analysis of primary data, it was clear that these actors with different interests in stem cell treatments were also dependent on each other for various activities such as the sourcing and extracting of cells, providing treatments, informing patients, seeking providers, and expanding a clinical practice or business.

In their actions and interactions it was also evident how stem cell treatments were embedded within existing and legitimate systems. There were links between public and private provision and within the private sector that involved seemingly unregulated stem cell practices. The clinical trial was also an agent of normalisation promoting hope among patients and/or caregivers who sought cures by any means. A public hospital's pilot study offered stem cell treatment of (autologous) bone marrow for muscular dystrophy — a treatment that promised little for an inherited, genetic disorder. The stem cell procedure itself was amenable to these micro and meso pathways of normalisation. Bone marrow was easy to extract and insert into the patient, said enthusiastic clinicians in order to alleviate any doubts that people might have had about stem cell treatments. Providers did not have to go very far either to source stem cells that were derived, in many cases, from the patients themselves.

The criteria for routine embedding of an experimental medical technology argued in literature, was thus, also present in the context of stem cell treatments. Established settings and systems were favourable to incorporating an unproven treatment. New relationships and networks were also created to activate and facilitate movement of stem cells and various actors. The popularity of a new or experimental technology is argued in STS as an outcome of both technical and social factors. Both these categories of the social and technical had operated in the normalisation of stem cell experimentation taking place at multiple levels, of which the micro, everyday engagements are emphasised in this chapter.

The subject of hope in biomedical developments, a running theme throughout this thesis, is illustrative of the STS argument of science and society as combined forces that shape futures of new medical technologies. In these normalisation pathways, scientific facts on stem cells were subsumed by hope for cures, and hope in turn kept the interest in stem cell treatments alive and active by downplaying uncertainty that reared its ugly head every time there was disappointment in the private negotiation of incurable conditions. The literature on hope argued how expectations invested in unproven medical treatments belonged not only to the private domain of individuals coping with illness but also operated at a larger scale. Brown argued that hope was strategically used by the biomedical industry in advanced economies to draw patients and investors into emerging markets, that nations like India have been eager to compete in and also attempted to build their own. The hopes and aspirations of individuals were therefore linked to markets and macro polices in the normalisation of

stem cell experimentation. In treatment routines, patient-clinician encounters, new and old networks, biotech companies and friendly clinical environments, different meanings were attached to stem cell treatments and its providers. These meanings, and the various compulsions that drove actors into engaging with stem cells can also be explained as effects of national and global policy initiatives in scientific research and development. The structural pathways of normalisation of stem cell experimentation discussed in the next chapter, shifts the focus onto the relationship between micro worlds and macro transformations. In analysing the various mechanisms by which unproven stem cell treatments were normalised, this chapter and the next reflect the arguments made in the literature on normalisation as an outcome of a process rather than the result of the technology's own making. To recall Valenstein's account of prefrontal lobotomy, the procedure was "catalyzed and shaped" by particular individuals "who, at critical moments" had a considerable influence "on the course of events" (Valenstein 1986:6). Valenstein's statement also points to the STS perspective of the "irredeemably human (and hence social) enterprises" that constitute science and technology, which therefore, must be "continually" challenged in their assumptions of "authority" (Edge 1995:5). These arguments made against technological determinism are still relevant today as unproven medical technologies like stem cells become popular in their offer of new avenues for hoping — for patient, doctor, entrepreneur, scientist and state.

Chapter three

The Role of the State and Media in Stem Cell Research and Experimentation: Structural Pathways of Normalisation

Introduction

"Today, biotechnology rules", stated Hacking (Hacking 2012:ix). He was referring to transformations in science since 1962 when Kuhn published his seminal work, *The Structure of Scientific Revolutions*. In Kuhn's time, physics was "the queen of the sciences" but that is no longer the case "in the teeming, present world of biotechnology" (Hacking 2012:ix). In the 1970s, breakthrough biomedical innovations in the U.S. such as recombinant DNA, not initially developed for commercial use, were later transformed into new sources of economic opportunity (Tyfield 2010). Faced with a fiscal crisis, rising unemployment and a growing aging population, industrialised nations looked toward the life sciences as an alternative source of capital (Tyfield 2010). New genetic technologies had the potential for growth and expansion of the pharmaceutical industry, which given access to advances in molecular-based knowledge could develop drugs for highly specific cellular or molecular targets. Using the recombinant DNA technique, for example, genes could be isolated and studied in ways that were not possible earlier. With these potentially marketable innovations in molecular biology in the latter part of the 20th century, there were great expectations in biotechnology from both state and industry (Hopkins *et al* 2007). The "economic ideologies" of "competitiveness" as necessary for innovation driven growth justified the expansion of biotech industries in the 1980s in advanced nations and also legitimised state led efforts in the commercialisation of scientific research (Birch 2006:1). Gaining competitive advantage through a knowledge economy developed into the "dominant political economic perspective" in Europe and the U.S. after the 1970s financial crisis. These significant shifts also influenced India's biotechnology policy (Birch 2006:3). The global "discourse around the importance of competitiveness" had entered the country's overall policy lexicon by the 1980s and 1990s when India expanded the presence of the private sector in healthcare, and initiated new policies that globalised its economy.

This chapter argues how state policies in certain sectors particularly health, drug development and biotechnology have had a direct bearing on the normalisation of stem cell experimentation in the everyday world of provider and patient. India, like other nations the world over, has invested public funds in the highly knowledge-based and capital-intensive field of stem cell research. According to Waldby, stem cells along with genes are this century's "new biological actors" and "potent icons of promised control over our biology and health" (Waldby 2002:306). "It's very cool doing work on something which could reproduce a whole organ", said a young scientist working at Institute X, India's most cutting edge, publicly funded institution for stem cell research (Interviewed 5.2.2014). According to the scientist, stem cells "in today's world" have become a "hot topic" and while India undeniably has other research priorities, to argue against state support for the field would be "incorrect" (Interviewed 5.2.2014). A fellow scientist disagreed:

> I don't think India should be spending so much on establishing something that other countries have already established. I think like establishing iPS generation, its pretty labour intensive and reagent intensive…I would rather collaborate (Interviewed 5.2.2014).

In the current climate of investment in science for future commercial gain, there is great pressure in countries like the U.S. for basic research to reach the clinic as fast as possible. According to Martin and others, "nowhere" is this focus on translation from laboratory to medical practice more evident than in "regenerative medicine", and the "exploitation of basic research" for product development has become a matter of considerable interest in governments across the world (Martin, Brown and Kraft 2008:29). India too, lists translational research as a key objective of its stem cell policy and the state biotechnology department has several private-public schemes to encourage greater involvement of industry (Salter *et al* 2007).

Establishing a clear-cut relationship between these macro level developments and micro narratives is a challenge for social theory, stated Waitzin, who attempted to resolve the issue by showing how the personal and the structural can "impinge on each other" in ways that may not be obvious to the actors involved (Waitzkin 1989:221). According to Waitzkin, the doctor-patient encounter, for instance, "masks a deeper structure that may have little to do with the conscious thoughts of professionals about what they are saying or doing" (Waitzkin 1989:220). By this statement he implied that behind the private realm of individual feelings, thoughts,

actions and motives are dominant ideologies defined as an “interlocking set of ideas” promulgated through state and non-state institutions that include medicine and the mainstream media (Waitzkin 1989:221).

The discussion in the pages that follow takes on the challenge of linking personal narrative with macro level policy. It also analyses how the media in advertising stem cell technologies has promoted policy-led commodification of healthcare, and hence, is also a structural force that has created the conditions for the normalisation of stem cell experimentation. The concept of normalisation in this study draws largely from existing ethnographies on various experimental medical technologies that are detailed in the literature review. The literature on IVF, for instance, revealed how the normalisation process was replete with anxiety and “contradiction”, features that were also present in the everyday world of the stem cell provider and patient (Franklin 1997:165). To normalise a new and relatively unknown technology, therefore, also implied the need to establish order and stability at the level of both individual and state. Franklin and Thompson, for example, described how IVF in the early stages of its introduction was normalised by patients in order to make sense of their worlds disrupted by social stigma, gender norms, hope and disappointment. Koenig too analysed the process of successful routinisation of a new medical technology as the final outcome of disorder and social disruption in the medical setting. Jasonoff, on the other hand, looked at broader national policy frameworks used to normalise biotechnology in the context of controversy and doubt among the public and policy makers on the future implications of new technologies. Bioethical regulation was an example of an organised macro level effort to alleviate fears in society on biomedical advancements by institutionalising considerations of social justice in research using human subjects. Instead, however, the application of bioethical principles and the routine use of procedures like informed consent were standardised in research settings in isolation of society’s structural imbalances such as unequal healthcare access. The discipline ultimately served the interests of industry and medicine rather than public health, its critics argued. The process of normalisation, stated Jasonoff, thus, achieved an unstable consensus among nations and various interest groups as controversies and uncertainties in the introduction of new biotechnologies with unpredictable futures still persist.

These writings that framed normalisation as a process of bringing order in individual lives at the clinic or at levels of government, reflected the writings of Foucault and earlier social theorists like Comte, both of whom despite varied perspectives,

understood normalisation or the term 'normal' as establishing order in the context of political, social or economic crisis. The normalisation of stem cell experimentation is also argued in this study within the framework of crisis in healthcare policy, and state attempts to curb unregulated practices through regulation. According to Comte, a society could be described as normal if it had reached a state of perfection, order and harmony by overcoming circumstances of extreme "crisis" that he believed plagued society in his time (Misztal 2002:194). A normalising society for Comte was thus moving from a state of chaos towards a state of "progress", "consensus" and "equilibrium" (Misztal 2002:194). According to Foucault, a state of order wrought through normalisation was not as desirable as Comte understood it to be. The process of normalisation for Foucault meant sustaining existing inequalities and asymmetries in power relations and also creating new ones. To normalise society, he understood as the use of various methods by authorities to bring individuals deviating from established norms into the realm of what was considered acceptable. A normalising power could be understood as both negative and positive, argued Foucault, for laws and regulations intended for protection, on the one hand, could end up further silencing the voiceless and creating new forms of control. Although Foucault was largely concerned with the question of " 'how' " rather than " 'what' " and 'why' " his analysis is relevant to understanding how normalisation processes of stem cell experimentation can also be viewed as an outcome of structural crisis, resulting in new ways of control over subjects—be they individual patients or clinicians (Foucault 1982:785-786). While subject formation is the focus of chapter four, the current discussion provides a structural analysis of normalisation, interjected and juxtaposed with narratives of respondents in an attempt to provide a broader framework of the process. This chapter is, thus, based on the premise that micro narratives of a phenomenon are not ends in itself but explain political, economic and social shifts at national and global levels that have enabled events, in this case normalisation, to occur.

1. Experimental stem cell treatments in India's commercialised biomedical health system

In the previous chapter we saw how stem cell provision was usually ensconced within routine practices of the clinic or hospital, big or small, whether in the form of a free research study, paid for treatment or that which was offered within quasi-legal arrangements. To recapitulate from previous chapters a few instances of stem cell provision: a liver specialist in a tertiary care, trust hospital treated patients with end stage liver disease; a spine surgeon in a single specialty hospital for spinal cord

injuries treated patients in a free clinical trial; a diabetes consultant at a charitable hospital offered stem cell treatment to his diabetic patients; an independent practitioner who headed a disability institute for children provided stem cell treatments for neurodevelopmental and neurodegenerative conditions; two vascular surgeons, one practicing in a charitable hospital and the other in a corporate institution both of whom treated patients facing the impending threat of leg amputation due to an advanced stage of a vascular disease.

The majority of patients and/or caregivers had paid for treatments in the private sector. In one case a patient was provided treatment in a public hospital at a subsidised rate via the private practice of a clinician associated with the hospital. The costs of the experimental treatment varied in the private sector. Independent medical practitioners like Dr. A, for example, charged about two lakhs for three 'stem cell doses'. The clinician attributed these high costs to laboratory payments that amounted to 1.25 lakh rupees for each patient. These were private laboratories that had invested crores of rupees in infrastructure, the clinician explained, but they had "limitations because they cannot charge you openly…they have not been authorised" by the government, he stated (Interviewed 25.1.2013). The patient organisation for muscular dystrophy charged lower rates than Dr. A. According to a caregiver at the organisation, five doses of stem cell injections were priced at 2.5 lakh rupees. The patient organisation's Director distanced himself from what he called "substandard" "commercial" stem cell treatments by claiming to provide "quality" stem cell therapy at cheaper rates, thus, in his opinion, mitigating the exploitative conditions of the healthcare market (Interviewed 27.11.2014). There was another case of reduced rates for stem cell treatment provided in a study on liver cirrhosis at a trust hospital. The study's research objectives did not preclude at least one patient being charged rupees 10,000 for each injection, a relatively lower rate than the market price. According to the patient, Mr. Sharma, the reason he was asked to pay for a research study was because the hospital "didn't have permission then. It was pending in the Ministry of Health, that permission [for the study] they got later" (Interviewed 26.4.2014). The treatment's results had been significant for Mr. Sharma who regained his health and returned to normal life. With end-stage liver disease he did not have the luxury of time and the study had been the only feasible solution. Current medicine could only offer a liver transplant but it was not an option for Mr. Sharma and his family. "With a transplant there are many after effects and its also very expensive", he stated (Interviewed 26.4.2014).

In addition to the cost of stem cell injections that amounted to lakhs of rupees, patients or caregivers also paid for questionable diagnostic tests such as PET scans and MRI's. Mr. and Mrs. Jain, mentioned in the previous chapter, were determined to not repeat the tests they had done back home in Mumbai before the study started in one of Delhi's public hospitals. They described the experience of the brain scan as traumatic for their son who had cerebral palsy. "He feels scared of the dark so we had to hold him while we sat inside", said Mrs. Jain (Interviewed 17.7.2014). The boy had been sedated "to make him a little dull" as the scanner took a complete 360 degree view of his brain (Interviewed 17.7.2014). The family did not return for follow-up appointments after the study was over. "Doing the reports was both painful and costly and we also didn't see much of a difference", the parents stated[1] (Interviewed 17.7.2014). Another caregiver, Vidushi, argued with her clinician, Dr. B, for suggesting a SPECT scan for her autistic child before the stem cell treatment.

> I just asked him, doctor what is the benefit of my doing a SPECT scan…can you do anything about it if you realise that there is something damaged…I'm ready to do all things without going through all of this, then why should I put my child through a SPECT scan. (Interviewed 19.1.2014)

These were caregivers not looking for a diagnosis. They already had one. "I know there's some problem that's why I'm here" Vidushi exclaimed (Interviewed 19.1.2014). Like other caregivers or patients of the study, she was looking for a biomedical cure for daughter with autism whose integration into society or routine life was not always smooth despite having resources to access the best schools. Options for special or integrated education in the country were limited and Divya and Seema who were also parents of children with autism, had enrolled in training programmes in special learning systems and methods so they could educate themselves to inform mainstream schools on their child's specific needs and also teach their children at home.

There were patients of the study, young and old, who were confined to wheelchairs and or lived a life of social exclusion. For example, two teenage boys with muscular dystrophy who died shortly after the interview, were unable to sit, stand or eat without support and had spent most of their short lives entirely depended on caregivers in the isolation of their homes. "No one comes to see him", said a mother of one of the boys and neither could they go out together as a family (Interviewed 26.11.2014).

[1] Most of this interview has been translated from Hindi.

The minds of some of the affected boys were, however, active like any other young person. People afflicted with MD usually have full cognitive function. Like many others with physical and/or cognitive disabilities, they had been barred from attending school because of their inability to climb stairs, run or play and think like other children. India is a “depressing place to stay”, said Vivek with MS, when comparing his experience with stem cell treatment in a region in China that had “wheel chair access everywhere” he stated (Interviewed 26.6.2014).

Removing stigma and building acceptance of disability in society requires long term, structural interventions at various levels such as education, physical or infrastructural access, psychosocial support and employment opportunities. These issues, however, get subsumed in the context of relatively new biomedical developments that are sold as quick fixes to the problems of living with intractable conditions. Disability movements in India and the world over continue to challenge the dominance of the biomedical model in policies that claim to enhance social inclusion of differently abled populations but on the ground have remained situated largely within medical terms. Proponents of the social model of disability believe its more effective than medicalised theories as the former works at “optimal opportunities for the person’s own capabilities to increase”, explained a special educator and director of an institute for children with disability (Interviewed 28.3.2015). For example, in the case of cerebral palsy she explained:

> There is brain damage so unless the system, the environment chips in that person can’t be left alone to say now you get on with it…. “If you can’t walk you can’t walk that's it. Now if you force me to do it I can’t do it. (Interviewed 28.3.2015)

The social model of disability might be easily misunderstood for being entirely opposed to active medical interventions for improving lives of people with special needs, the specialist stated, but “we don’t give up on the person…ever”, she clarified. On the contrary, “we must have high expectations of people, we must give opportunities, we must allow participation but we do know what would be near impossible” she argued, referring to the new therapies that she claimed “make it sound like it’s working on its own to the exclusion of everything else” (Interviewed 28.3.2015).

Clarke and others described biomedical advancements as “jewels in the clinical crown” that function as “vectors of biomedicalization” (Clarke *et al* 2003:161-162). According to the authors, biomedicalisation is a step ahead of medicalisation that has

already occurred in conditions such as mental health or in the context of bodily enhancement for bodily parts and features considered "undesirable" due to perceived difference (Clarke *at al* 2003:164). Taussig and others, for instance, described how limb-lengthening procedures used by some surgeons to treat dwarfism was an example of an extremely specialised medical skill used to fulfil the patient's "desires for genetic improvement" (Taussig, Rapp and Heath 2005:195). The response to this controversial procedure by the Little People of America (LPA), an advocacy group for short persons, reflected the dilemma experienced by marginalised communities who are caught between the choices of conforming to mainstream biomedicalised approaches, yet simultaneously showing organisational strength to "resist" the power of new technologies (Bevir 1997:78 cited in Taussig, Rapp and Heath 2005:196). Taussig and others observed that although there were conflicting opinions within the LPA community on the role of enhancement technologies, their different views were still confined to "discourses of biotechnological individualism" (Taussig, Rapp and Health 2005:200). In other words, the diverse responses of the LPA on "technological interventions" were framed within arguments of individual freedom of choice to participate or decline involvement in biomedical innovation that was both defining the meaning of "perfectibility" and also offering solutions to achieve it through the market (Taussig, Rapp and Health 2005:196).

In highly commercialised health systems such as the U.S., solutions to human suffering are largely sought by the "control and repair of individual bodies", stated Lock (Lock 1996:210). The hope from medical technologies such as stem cell science strongly resonates with definitions of health and wellbeing that are informed entirely by the domain of medical intervention even when medicine has nothing to offer. Stem cells are injected into the human body with the intention of regenerating dead or dying cells thereby creating new tissue or repairing damaged parts. The premise is real and has the potential to be revolutionary but only if and when cures are found. "There is something there" in stem cells, caregiver Seema[2] thought, when she started her arduous search for treatment options for her autistic daughter (Interviewed 26.11.2013). Later, Seema changed her opinion on experimental stem cell treatments when her daughter almost died of meningitis in the course of it. Seema had stored her younger son's cord blood in one of India's leading cord blood banks in Gurgaon with the intention of using it for her daughter. The cord blood bank had coordinated directly with Dr. B's centre, in Delhi, for the stem cell treatment. After the second stem cell infusion when Seema's daughter fell ill at night, she sought

[2] Most of Seema's interview has been translated from Hindi.

medical advice from a pediatrician she found in her neighbourhood in Dwarka. The medicines the clinician prescribed over the telephone did not work and so Seema called her doctors back home in Bikaner for their opinion. Meanwhile, on the recommendation of Dr. B, Seema visited another clinician in South Delhi who prescribed medication for meningitis. Seema was made aware of this diagnosis only later when she admitted her daughter in a hospital in Dwarka. From Dwarka, Seema rushed her daughter to one of Delhi's leading tertiary care institutions where the child was treated until her full recovery.

Today, Seema would prefer to not look back on her experience with stem cell treatment that she recounted with horror and dismay. Dr. B took no responsibility for the events that followed the treatment. In retrospect, Seema recalled the conditions of the nursing home where the stem cell procedure was done as "pathetic", even worse than the "general hospitals" in Bikaner (Interviewed 26.11.2013). Dr. B's assistant blamed the episode on the cord blood bank's sub-standard storage facilities. Other clinicians, who Seema had consulted, held her responsible for her daughter's illness. "They all told me that why did you go for such kind of experimentation...your child is not a guinea pig", Seema stated (Interviewed 26.11.2013). "I think I was almost broken. Everybody, even my husband was blaming me that it was your decision", she said (Interviewed 26.11.2013). The emotional costs had been high for Seema. She had forgiven her family explaining their response to the ordeal as "human nature", but she had lost faith in the health system. "Now I know there isn't any point in going to doctors whether it is for autism…or for CP [cerebral palsy]" (Interviewed 26.11.2013).

Seema's encounter with stem cell experimentation could be analysed as a story of personal drive and individual choice in the face of debilitating circumstances. Any negative experience she might have had with healthcare providers could therefore be argued as unfortunate outcomes of poor personal decisions and perhaps, purely bad luck. Yet, Seema's story and those of other respondents, indicated systemic tensions, resistance and unaccountability of healthcare provision—of irrational tests and random pricing, of patients resisting their doctors, of the presence of an unregulated biotech industry profiting from clinicians, of clinicians profiting from patients, of patients seeking cures when there were none, of the medical profession dismissing the practices of its own members. These features that characterised stem cell provision were not unique to it. Rather, Seema's narrative of personal blame exemplified a neoliberal logic prevalent in healthcare that expects accountability and

responsibility to lie primarily with the patient-consumer. Stem cell treatments can, thus, be argued as an example of commodification of healthcare at its extreme, with experimentation a recent addition to medical interventions used regardless of clinical benefit or patient safety. At least "50" percent of an average family's spending on health in India today is due to "irrational or unnecessary" medicines, diagnostic technologies and procedures, most of which takes place in the private sector (Mahal, Varshney and Taman 2006;Sengupta 2013:3). The public health sector, crippled by decades of policy neglect, has had to compete with private health services without adequate financial, infrastructural and human resource support. The patient, thus, inevitably ends up in the private sector and the general perception of private provision equals better quality care has evolved even though the sector is unregulated and varies in terms of quality, pricing, access and availability[3] (Basu *et al* 2012).

Private providers in India's health system did not always imply rapacious, profit-driven health care services, argued Sengupta and Nundy. "Many of the services provided were of exemplary quality, especially those run by charitable trusts and religious organisations" (Sengupta and Nundy 2005:1158). The difference from the 1980s-1990s, however, was the repositioning of healthcare in policy and in ideological orientation that led to a redefinition of the patient's role in seeking health services. Under India's economic reforms in the 1990s, the market was given a greater role in social sectors. In healthcare, for example, user fees were introduced in public hospitals, the poor were offered narrowly defined clinical packages and larger corporate entities, on the other hand, were offered incentives to expand their business interests in healthcare. "Smaller" private players that were already integrated within India's health system were forced to compete with corporate enterprises that have increasingly absorbed the latter including independent practitioners and public sector doctors[4] (Rao 2004; Qadeer 2011:40; Baru 2016). The

[3] A systematic review that compared the performance of private and public healthcare in low and middle-income countries found that the private sector was not any "more efficient, accountable, or medically effective than the public sector" (Basu *et al* 2012:1). The study's findings contradicted "prevailing assumptions" on the private sector as it found the latter to be less efficient than public hospitals due to high drug prices, "perverse incentives" for diagnostics, higher "risks of complications" and poor regulatory measures (Basu *et al* 2012:10).

[4] Private institutions do not operate entirely in isolation of public services. There are several ways in which the two sectors are linked. Public sector doctors run private practices, public hospitals refer patients to private diagnostic centres and specific policy developments that have linked public insurance schemes such as the Central Government Health Scheme (CGHS) to include private hospitals have boosted private sector demand and brought private and public health sectors much closer (Srivastava 2017; Baru forthcoming 2018).

larger private institutions with greater bed occupancy claimed to offer global standards of care with technology imports or newly available devices of which imaging machines such as CAT scans and heart-lung equipment occupied 50 percent of the total equipment share (Baru 2005). With these technologies available for those who could pay, the patient has been increasingly viewed as a consumer and policies for more private sector involvement in the 1990s functioned on the market logic of increasing competition across and within sectors. This understanding of a health service mobilising consumer choice and generating patient-customer satisfaction has risked greater inequalities in healthcare worldwide including the welfare-based provision of U.K.'s National Health Service (Sturgeon 2014). In India there is sufficient evidence of structural adjustments in India's economy having only intensified the existing "crisis" of India's health system, already challenged by regional, caste, class and gender disparities (Ritu Priya 2005:54). For instance, the National Sample Survey of India in 1998-99 indicated that 40 percent of hospitalisations in the country resulted in indebtedness (Qadeer 2010). Household spending on diagnostic services almost doubled in the reform years and also later from 1999 to 2000. This spending on diagnostics "accounted for one fourth of the *increase* in the *share* of" healthcare expenditure faced by households at this time (Mahal, Varshney and Taman 2006:187). Among the possible reasons for increased spending, the authors believed, could be the availability of medical technologies in greater numbers due to intensified imports after liberalisation. According to Baru, imports of medical equipment had increased substantially at this juncture with the 1997-1998 budget announcing a further reduction of duties (Baru 2000 para.10). By 1998, multinational firms like Siemens and Philips had also set up shop in India to produce medical equipment like ultrasound machines and scanners (Baru 2000). Medical practitioners received "commissions" by private diagnostic services for referrals that ranged from 10 to 30 percent, which could also account for an increase in the use of diagnostics in the private sector (Mahal, Varshney and Taman 2006:187). While rising incomes in the 1990s also created more demand for modern technologies, the provision of "free" diagnostic tests for both inpatients and outpatients declined in the years 1986-1987 and 1995-96 (Mahal, Varshney and Taman 2006:187).

Duggal and Gangoli argued how "new medical technologies have helped complete the commodification of health care" in India (Duggal and Gangoli 2005:11). In this process of commodification, the asymmetry in access to a new technology has not

only been monetary but class and gender also distorted priorities in the introduction and diffusion practices of new technologies. While the issue of primarily middle class access to stem cell treatments is the focus of the next chapter, it is relevant to mention here that medical technologies introduced without considerations of epidemiological data, population needs and socio-economic contexts is a historical feature of India's national health programmes and remains challenged by public health activists and critics of health policy today. The history of reproductive technologies is a case in point. From the 1950s, global and national preoccupation with controlling India's population resulted in the disproportionate distribution of resources for family planning in relation to the rest of healthcare. From occupying 15 percent of the total healthcare budget in the sixth Five Year Plan, family planning spending increased to 24 and 35 percent in the two successive plans that followed (Qadeer 2000). Family planning objectives focused mainly on introducing contraceptive technologies for women in the absence of other key and complementary clinical and non-clinical considerations. These included questions on feasible follow-up mechanisms and measures for evaluation of safety and efficacy in contexts of non-existent primary health care services for many, poor nutrition among women and the general lack of control in everyday living experienced by those targeted. In the 1980s, new hormonal injectable contraceptives such as Depo Provera with known and controversial evidence side effects were introduced when problems with the earlier invasive but relatively safer birth control methods had not yet been resolved (Sathyamala 2000; Datta and Misra 2000; Rao 2004). Protests by women groups in this period against the government introducing these new contraceptives "did not stem from a Luddite distrust of technology, nor from a post-modern distrust of a modernizing state, nor…from perhaps legitimate fears of" multinational corporations exploiting India's large market, argued Rao (Rao 2004:209). On the contrary, there was enough evidence on the "misuse" of existing contraceptive technologies (Datta and Misra 2000; Rao 2004:209). Hormonal contraceptives continue to be introduced today to poor women throughout the developing world, even though the risks that include acquiring HIV are now well known (Green 2017).

Circumstances of "poverty, powerlessness and lack of access to information and services" made women "victims" of population control technologies (Rao 2004:204). Assured a wide range of contraceptive methods through policy frameworks of reproductive choice, the issues of women empowerment become meaningless in the absence of social change. Those better off meanwhile were no less vulnerable in the

face of options available to enhance their fertility through the market. The literature review discussed in detail Franklin's analysis of IVF and how "new uncertainties" in addition to social pressures of motherhood were produced for women undergoing treatment (Franklin 1997:10). The women described by Franklin, also created enterprising ways of coping with the emotional and physical hardship that the now common treatment entailed, making IVF a "complex" process full of hope and yet beset with failure (Franklin 1997:11). Medical procedures like IVF that were included in the category of "new reproductive technologies" are no longer new in India either, just as sex determination technologies like the ultrasound have also been normalised in antenatal care across sectors (Sama 2008; Kaur 2013 para.5). Both these technologies, unlike experimental stem cell treatments, have their place in the medical repertoire of reproductive problems. The ultrasound was developed to detect foetal abnormalities and IVF was an option for women unable to conceive. Both technologies offered women the potential to overcome the emotional and physical stress of pregnancy or non-pregnancy, showing a "way out" of oppressive structures of patriarchy or a way of meeting social pressures of motherhood (Franklin and McNeil 1988:548). In "the "short shrifting", however, "of social and psychological factors as playing a role in disease", scientific progress "is not all pluses", argued Lown, a cardiologist (Lown 2007:40). The condition of infertility is a case in point and exemplifies Lown's argument. Secondary infertility[5] that is defined as the "inability" of childbirth "after one or more initial births" is a preventable condition and more common in India than primary infertility or complete sterility. This fact is overlooked by lucrative practices in reproductive technologies (Qadeer 2010:15). The option of adoption is also forgotten in the offer of genetically related offspring by IVF that is sold regardless of the treatment's clinical realities that include a range of medical risks[6]. The choice of using medical technologies like IVF can be liberating for women, stated Franklin and McNeil, but it also "forces …individual solutions to social problems" (Franklin and McNeil 1988:548). This point was also emphasised by Kaur in her analysis of the link between "relative prosperity and sex selection" (Kaur 2015 para.8). The ultrasound was more likely to be used among the middle and lower middle class, in other words, the "upwardly mobile", as a means to exercise their preference for a male child (Kaur 2015 para. 9). Discussed in detail in the literature

[5] According to Qadeer, secondary fertility can be caused by complications during childbirth, "pelvic infections, STD, RTIs and endometriosis, repeated pregnancies associated with resulting high infant mortality, inadequate facilities…in pre and post partum care and the poor state of general health". Other factors such as "under-nutrition", "environmental" conditions and improper use of contraceptives can also cause secondary infertility (Qadeer 2010:16).

[6] Risks include Ovarian Hyper Stimulation Syndrome, multiple births with accompanying risks and ectopic pregnancy (Sarojini, Marwah and Shenoi 2011).

review, the ultrasound's use for low-risk women has not proven necessary and yet a huge market has emerged. "New technologies appear faster than they can be controlled", stated Kaur, but it would be foolish to blame technology for the choices it enables" (Kaur 2015 para. 5).

The routine offering of stem cell treatments and UCB banking in India today can be added to an entire range of unproven or controversial medical procedures that were introduced into clinical practice regardless of sufficient evidence of safety or benefit. In the case of pre-frontal lobotomy, for instance, the medical intervention at the height of its popularity became an easy option for the public health problem of mental disorders that required social solutions in equal measure. The reasons for the acceptance of the brain procedure were described by Valenstein to be as complex then as they are today in contemporary medical technologies such as stem cells. The idea of storing cord blood for autologous use in some future time captures another kind of human vulnerability, of those who can afford to pay. With aggressive advertising techniques that involve patient-doctor encounters comprising gynecologists and their clients, cord blood banking is a term used almost synonymously with stem cell treatments among India's urban middle class. The future applications of privately stored CB stem cells for clinically unproven conditions, a dubious and controversial proposition, is nevertheless sold to the public as reason enough to pay for its storage. The rates for storing cord blood in private banks in India are competitive. Clients are offered different payment options and monthly installment schemes. For example, Lifecell's " 'Baby Cord' " plan offered UCB storage for 21 years with a monthly installment of rupees 3,500 over a two-year period (Shukla 2009 para.16). With currently limited clinical use, stored cord blood "usually stagnates as stock" in India's banks, stated Patra and Sleeboom-Faulkner (Patra and Sleeboom-Faulkner 2016:272). The authors found that UCB was likely to circulate outside the bank without the commercial entity making full disclosure to paying clients. The exact nature of UCB's uses other than its advertised objective of storage for securing family health was not, however, clear to them (Patra and Sleeboom-Faulkner 2016:). The findings of this thesis could perhaps throw some light on the various possible networks that use privately banked UCB for unproven and unregulated stem cell treatments. For instance, independent private practitioner Dr. E, in Agra, had sourced UCB derived Mesenchymal stem cells from a private cord blood bank run by a life science firm owned by one of India's leading business houses. Global Life Sciences located in Mumbai was also providing its service of processing stem cells to Dr. D in Dehradun (see chapter two). The firm also housed

a public CB bank, although the practice of large scale banking of UCB for allogenic purposes is not found in India and the impact of public banks as a public service is miniscule (Patra and Sleeboom-Faulkner 2016). The country's private UCB banking industry, on the other hand, at an estimated market value of 2700 crore rupees is expected by the year 2020 to increase India's share in the global market in UCB banking to 17 percent (Patra and Sleeboom-Faulkner 2016). The country's high annual birth rate of 26 million births, analysts claim, could also potentially make India the world's largest storehouse of umbilical cord blood (Shukla 2009).

The writings of Brown, Michael, Martin, Borup and others that constitute "the basis for a sociology of expectations" in science and technology, were useful in understanding how the stem cell industry has managed to attract the interest of clients and business despite the uncertainty in stem cells realising their curative potential (Brown and Michael 2003:3). The literature review discussed how the "regime of hope" has proven integral to the legitimacy of the biotechnology industry and emerging markets in the biosciences (Brown 2005; Moreira and Palladino 2005). "Expectations", in other words, have assumed so "crucial" a role that the technology's "future" can "depend" on it (Brown and Michael 2003:3). According to Brown and Michael, the hopes or expectations invested in clinically uncertain medical technologies are not, however, the same for everyone and could vary according to where the actors are located in relation to the source of "knowledge production" (Brown and Michael 2003:12). Scientists, for example, closely involved in "the production of " 'facts' " are more likely to be doubtful about the "future therapeutic value" of research than lay actors (Brown and Michael 2003:13; Borup *et al* 2006). As far as the state and industry are concerned, several authors discussed in the literature review argued how the "rhetoric of hope" was used to the advantage of these actors to ensure the smooth entry of controversial technologies (Mulkay 1993:724). British parliamentarians, for example, who supported hESC research used "hope" to justify its advancement (Mulkay 1993:726). In state support of stem cell science was "hope for a better world" they implied, and in this assumption of a better world created though science, Mulkay argued, was also embedded the notion of "controlling that world" (Mulkay 1993:726). The U.K. was among the first nations to introduce a law for hECS research. The country's Human Fertilisation and Embryology Act of 1990 was based on the recommendations of an enquiry committee set up as early as 1982 to deliberate on technologies of IVF and embryology (Wilson 2011). The Act that that permitted the use of supernumerary embryos or those left over from IVF and significantly allowed the use of embryos, not

more than two weeks old for research, were rules also adopted by India for hESC research.

Linking biotechnology to economic growth and political power, Jasonoff reminds us, is not a feature of only contemporary governance and neither is the use of "human and biological sciences" for furthering human progress and exercising control over populations (Jasonoff 2006b). Colonising powers documented natural resources and categorised human subjects on the basis of biological difference in order to rule more effectively and prudently. Biotechnology today can assume a similar function of "possible imperial constructions" Jasonoff argued, but within an entirely new commercial and global paradigm (Jasonoff 2006b:276). As understood in contemporary times, "biotechnology is much newer", defined as the range of "manipulative techniques based on the alterations of the cellular and subcellular structures of living things enabled by the 1953 discovery…of DNA" (Jasonoff 2006b:276). Rapid advancements from the 1970s onwards in medical—as well as agricultural—biotechnology led to further manipulations of human biology and challenged fundamental notions of human nature and how humans had always understood themselves. In the 1980s, the ambitious Human Genome Project (HGP), for example, claimed it could expand existing knowledge on the human species to unprecedented heights. In 2001, the HGP published the "complete sequencing of the genome" in *Science* and although this enormous scientific endeavour fell short of its expectations[7], it ultimately signalled the arrival of "big science American-style" (Jasonoff 2005:234). By 1988, there were 300 biotechnology companies in the U.S. and by 2004 the industry was worth 80 billion dollars (Ernst and Young 2004 cited in Hopkins *et al* 2007). Several laws and policies were initiated from the 1980s in the U.S. to facilitate the commercialisation of research and further extend the monopoly rights of patent holders. For instance, Thomson's path breaking research in 1998 that emerged from a laboratory in a U.S. university was partly funded by Geron Corporation that demanded in return sole marketing rights of the stem cell technology (Marshall 1998).

As advanced nations recognised the commercial potential of biotechnological innovations, the commitment they made to biotechnology also demanded a reassessment of their national and global identities in the context of scientific

[7] Genetics research appears to be more complex than envisaged at the start of the HGP. The knowledge gained from the HGP did not result in a radical transformation in medicine as was hoped. Cures for various conditions including Alzheimer's and cancers based on genetic variants have not yet been found and currently research on the subject provides, for instance, limited information on genetically derived risk factors (Wade 2010).

advancements and the potential for controversies and uncertainties (Jasonoff 2005). Several new developments that occurred as a response to biomedical innovation such as the discipline of bioethics proved useful in helping governments navigate the political and moral quandaries they faced as biotechnology's potential to intervene further and deeper into the human body was progressing apace. From Jasonoff's comparative study (see literature review) of biotechnology in advanced industrialised economies, we learnt how the highest legislative body in the U.S., in the Diamond v. Chakrabarty case, manipulated understandings of what is natural and man-made in order to facilitate the commmercialisation of a biological organism previously unthinkable in patent law worldwide. This judgment along with other policy moves was significant in laying the foundations for a life sciences industry in the U.S. that would affect global standards for conducting biomedical research. The U.K. in comparison showed more reluctance in its drive towards commercialisation, even though it gave its scientists among the world's most liberal policies for human embryonic research. Despite common developmental goals, each country defined the future of their biotechnology sectors differently, that in turn was crucial in the envisioning of the nation's future (Jasonoff 2005). The U.S. federal ban in 2001 on public funds for future hECS research caused concern among American scientists who feared that countries like China and India would pose a serious threat to world leaders in biotechnology (Friedman and Marcovitz 2009). In India too, there was "excitement" as a result of President Bush's "decision", stated scientist B at institute Y (Interviewed 6.2.2014). According to scientist B, even though laboratories working with hESC cells already existed in India when the U.S. government announced restrictions of public funds for the field, the ban provoked an "interest" in stem cell research in the country and the world over "in a way" that was not previously experienced or known (Interviewed 6.2.2014).

Building a biotechnology sector worthy of global competition in the life sciences was among the main objectives of India's Department of Biotechnology (DBT, GOI 2009-2010). The following section discusses how India's policy in stem cell research and biotechnology in general was also conceptualised within state agendas and future goals of national development, economic growth and aspirations of leadership in the global knowledge economy. India's biotechnology sector emerged stronger from the country's economic liberalisation polices and the adoption of more globally oriented development goals (Lofgren and Benner 2010). The country's successful pharmaceutical and information technology sectors were seen as advantageous to developing a globally competitive knowledge economy (Salter *et al* 2007). The

globalisation of clinical research, and the harmonisation of rules and regulations with international regimes that included intellectual property laws also facilitated the growth of a biotechnology industry that benefited from the country's already privatised and commercialised health system. All of these policy shifts and developments intersected with the normalisation of stem cell provision, having allowed the practice to percolate within systems and structures, new and old. The pages that follow will discuss how macro developments affected individual choices, personal goals and actions with regard to stem cell treatments in ways that were obvious and practical, and also implied in individual wishes, ambitions and anxieties.

2. India: a "global leader in science"[8]

The country's information technology sector "stands for 'India Today' " and "BT (biotechnology) stands for 'Bharat Tomorrow' " said Vajpayee, India's Prime Minister from 1998 until 2004 (Bharadwaj and Glasner 2009:30). This rhetoric by state leadership proclaiming lofty expectations from biotechnology is evident across several policy documents that envision the nation as a future scientific power and innovation hub. Discussed in the literature review, these include government Five Year Plans, the DBT's vision document and annual reports, publications of the Science Advisory Council and government commissioned documents like the ABLE report. The period of the 1980s and 1990s was a "watershed in science" in advanced economies due to the "extent and nature of globalization and commercialization of scientific research" (Mirowski and Van Horn 2005:503). These years in India also witnessed major changes when concerted policy and legislative decisions indicated a shift towards not only greater privatisation of social sectors but also a shift in policy focus between sectors such as from agriculture to medical biotechnology (Lofgren and Benner 2010). In establishing a National Biotechnology Board in 1982 and later setting up the DBT in 1986, India "formally" laid the foundations for the country's biotechnology sector (Salter *et al* 2007:81). While its research and development (R&D) expenditure had always focused on traditional funding areas such as defense and atomic energy, the DBT's budget increased from 96 million dollars at the time of its establishment in the 1980s, to about 358 million dollars in 2004-2005 (Chaturvedi 2005:26). Within the life sciences, the DBT's funds for medical biotechnology increased from 13 percent of its total budget in the Ninth Five Year Plan (1998-2002) to 36 percent in the Tenth Five Year Plan period (Salter *et al* 2007:83). This greater

[8] The Science Advisory Council to the Prime Minister, the country's highest body for science and technology policy described India as a "global leader in science" in the title page of its 2010 document (DST, GOI 2010:3).

attention to health biotechnology was also reflected in an increase in the share of health biotechnology firms from 24 percent in 2001 to 35 percent in 2003, with the largest concentration of these firms found in the states of Andhra Pradesh, Maharashtra, Delhi and Karnataka (Arora 2005; Salter *et al* 2007).

In the current and continuously evolving global scenario of biomedical research, the role of science and technology in India today is different from the post-independence period. In the 21st century, modernisation through biotechnology is not seen as an end in itself but as a means to also participate in cutting edge innovation, in global trade and the emergence of new markets. Ong analysed how investments made by Asian economies in biotechnology manifest a "deep nationalist fervor" to get ahead of " 'the "West' " and also "potentially surpass" it (Ong 2010:5). A senior scientist (Scientist C) whose major role was "policy drafting" at Organisation Z—India's highest body for the promotion, support and organisation of biomedical research—described how government departments have always ensured that India kept pace with "innovative technologies" in "areas of medicine…coming from any direction" (Interviewed 10.9.2014):

> …after the human genome sequence…survey was...disclosed…even the Department of Biotechnology as well as other government agencies like ICMR took a proactive role in starting a task force on genomics and molecular medicine (Interviewed 10.9.2014).

By 2001, the ICMR had funded 117 projects in the field of genomics. In light of new developments in "emerging branches of molecular medicine", the "hue and cry" raised in hESC research in the U.S., and the sensationalising of cloning Dolly, the sheep, the thinking was, said Scientist C, "that there has to be a policy in place, there has to be a direction given to scientists and physicians working in the field" in India (Interviewed 10.9.2014). The ICMR, in 2002, called a "brainstorming session" inviting various government stakeholders that included the Drugs Controller General of India (DCGI), the key regulatory and licensing body for research in marketable products. The outcome of the session was a "booklet" which became the blueprint for India's "first framework…for stem cell research and therapy" said Scientist C, and served as a guidance document for the initiatives that followed (Interviewed 10.9.2014). In 2005, the DBT together with ICMR launched a "national stem cell initiative" with the objective of funding and promoting therapeutic uses of stem cells, and also building

"'stem cell city clusters'" (Salter *et al* 2007:75). In the same year, a national task force on stem cells was established to implement the DBT's stem cell policy.

Although there is no information on budget allocations specifically for stem cell research or regenerative medicine, both the DBT and ICMR are key bodies involved in stem cell policy, regulations and funding. While the ICMR, that operates under the ministry of health and family welfare, supports basic research and funds mainly investigator led clinical trials or those that are not commercial projects, the latter is the mandate of the DBT. The DBT which is the largest central government funding agency in the life sciences falls under the purview of the ministry of science and technology that also runs the departments of scientific and industrial research (DSIR) and science and technology (DST). Government funding for health research is divided largely between these two ministries and their respective departments (Chaturvedi 2005; Wilson and Rao 2012). Each funding body, across these ministries, manages a range of autonomous public research institutes in which majority of health related R&D in the country takes place today (Wilson and Rao 2012). The DBT's autonomous institutes involved with stem cell research include the National Centre for Cell Sciences in Pune, the National Brain Research Centre in Manesar, Gurgaon and the most recently established inStem or the Institute for Stem Cell Biology and Regenerative Medicine in Bengaluru, India's premier institution in the field (DBT, GOI 2009-2010). InStem, in addition to its own research objectives, also functions as an umbrella body for two other projects: an extramural funding programme meant to support research in stem cells across the country and a partnership with the Center for Stem Cell Research at the Christian Medical College in Vellore (inStem 2010). Located on the grounds of the National Centre for the Biological Sciences (NCBS), inStem together with NCBS and the Centre for Cellular and Molecular Platforms (on the same campus) constitute the Bangalore Bio-cluster. Bio-clusters are an important component of national and state biotech policies particularly in the technology hubs of Bengaluru and Hyderabad. The clusters are envisaged as state-of-the-art infrastructural projects that combine work and lifestyle, emulating high-tech cultures created in specific regions of the world such as California's Silicon Valley in the U.S. (Bound 2007). Indian scientists working abroad are encouraged to return to India to build their careers in such spaces that hope to match global scales in content, form and symbolism. The DBT in its attempt to lure scientists back home set up a "re-entry grant" in 2008, known as the Ramalingaswami fellowship that targets scientists of Indian origin, interested in research positions in biotechnology (DBT, GOI, 2009-2010:27). In the same year, the

DBT also announced its collaboration with the U.K. based Wellcome Trust – a 140 million dollar grant for scientists with an annual salary package between 16,000 to 30,000 dollars a year, for a period of three to five years with the choice of working in any Indian institution (Bhattacharjee 2008).

"I could do things which I never would have done elsewhere", said a basic scientist who had trained abroad but returned to India to work at institute X, one of DBT's autonomous institutions for stem cell biology (Interviewed 6.2.2014). Basic science opportunities are better in India according to another scientist at institute X, who believed that her research would most likely "not be funded...in the U.S. because its not exactly translational research" (Group discussion 5.2.2014). Institute X was established during India's 11th five-year plan period (2007-2012) when the expansion of existing research institutions and establishing new ones based on innovative governance models was among the stated goals for the biotechnology sector in the Plan's working group report (Working Group, DBT, GOI 2006). Institute X was, thus, an outcome of a policy goal to build "new generation institutions" (DBT, GOI 2009-2010:161). Its modern architecture, glass walled, open layout laboratories represented the vision of India's new public institutions as forward thinking centres in science, professional attitude and visual appeal. Scientist A, a laboratory head at institute X, explained its vision:

> The lab we have here is an open plan design, so whether you're working on …little regenerative organisms or…human embryonic stem cells they're all sharing the same space. So that's all a part of this idea of collaborative philosophy so you can talk to each other and you know get new ideas. (Interviewed 6.12.2013)

Stem cell institute X was located in close proximity to the prestigious and older science research institute Y. According to Scientist A, from its very inception the message of institute X was visionary for Indian science as it encouraged a "clash of ideas" from which "lateral" solutions could emerge fostering a kind of knowledge production that was beyond the capability perhaps of an "individual lab" (Interviewed 6.12.2013). In other words, problems in stem cell research need not be solved only by a "stem cell biologist" but a "chemist" or even an "engineer" could be involved, the scientist explained and "so there's an element of risk" in the research process (Interviewed 6.12.2013). Scientists at both institutes worked on mouse models and human-derived embryonic stem cells as well as adult stem cells that included iPS cells, with objectives of understanding the fundamental basics of stem cell biology.

With regard to clinical applications of stem cells, Scientist B's laboratory at institute Y, for example, was studying the early onset of Alzheimer's disease by creating "disease models using patient samples" (Interviewed 6.2.2014).

The kind of collaborative set-up for stem cell research described above was a stated policy objective of India's stem cell task force. According to Scientist B, its former member, the task force in recognising the increasingly "multidisciplinary" nature of biology had included in its agenda—other than funding—the importance of attracting talent from different areas to stem cell research (Interviewed 6.2.2014). A scientist who moved from the U.S. to work at institute X gave reasons for his return:

> I never would have probably gone to stem cell research unless I came here, that was the big draw for me so that I could do things which I never would have done elsewhere. (Interviewed 6.2.2014)

Some laboratories in these institutions had partnered with organisations outside. These were departmental tie-ups that functioned independently of a larger institutional association. Scientist B's laboratory, for instance, was in collaboration with a mental health institute for acquiring blood samples for its research on Alzheimer's disease (Interviewed 6.2.2014). Meanwhile, the centre for skin biology at institute X had partnered with the cosmetic firm, L'Oreal, for a research venture that involved investigating molecular mechanisms of the skin with the future goal of translation into everyday use (inStem 2017). Translational research in health biotechnologies such as stem cells is a priority area listed by the DBT as is promoting basic research. The term translational usually implies the "bench-to-bedside" model or the transfer of basic scientific knowledge into clinical applications or patient use (Martin, Brown and Kraft 2008:30). It is a complex process involving several stages that starts from laboratory research followed by clinical trials, which if successful could lead to results introduced into clinical practice (Hostiuc *et al* 2016:1). Since the sponsors of global clinical trials today are largely pharmaceutical companies, the biomedical-industry complex, also evident in India's health system, is an important relationship for translational science (Baru forthcoming 2018). At the Indian Science Congress in 2012, the Prime Minister Manmohan Singh asked industry to spend more on R&D and called for greater private sector assistance in increasing investment in science from one to at least two percent of India's GDP (*India Today Online* 2012). Public funding constitutes more than half of R&D investment in India (Bound 2007) whereas in the U.S., for instance, federal funds

amount to only about one-quarter of total R&D investment, indicating a greater presence of the private sector in the country's R&D expenditure (Wilson and Rao 2012:15-16).

Attempts to increase industry involvement in biotechnology research in India are evident in the various schemes and initiatives of the DBT. In 2007, the Department's Development Strategy report announced 30 percent of its funds for public-private initiatives (DBT, GOI n.d.; Wilson and Rao 2012). Among these public-private schemes was the Biotechnology Industry Partnership Programme (BIPP), a cost-sharing initiative in the form of loans and grants for high-risk innovation in biotechnology. In keeping with the DBT's statement in its Development Strategy that included stem cells among the areas essential for India "scaling new heights" (DBT, GOI n.d.:8), the BIPP also supports stem cell biology and tissue engineering projects. Started in 2008, the Programme intended to make "Indian industry globally competitive" and generate intellectual property in "frontier, futuristic" technologies (DBT, GOI 2009-2010:128). Although the government bears the significant risk of BIPP, contributing between 30 to 50 percent to the grant-in-aid, the intellectual property rights belong to the company and the publicly funded scientist who participates in this initiative receives a royalty on the patent (DBT, GOI, 2008:12). According to the working group report of the 12th Five Year Plan, 51 companies that included small, medium and large enterprises benefited from the BIPP scheme (Working Group, DBT, GOI 2011). Another source of funding in the form of venture capital for biotech start-ups or new entrepreneurs is the Biotech Consortium of India Limited (BCIL). The BCIL is a public limited company set up soon after the establishment of the DBT in order to accelerate relationships between research institutes and the industry (Salter *et al* 2007:84). Unlike the U.S., where venture capitalists are a dominant feature of the biotechnology industry, in India they have made only gradual inroads in the sector with individual states attempting to increase their presence. For example, the State of Karnataka's Millennium Biotech Policy II of 2009 announced a collaborative "bio-venture fund" of Rupees 50 crore with a "professional" venture capital company in order to support "hi-tech areas with strong social relevance" such as stem cell biology (Government of Karnataka n.d:12). Karnataka is home to some of India's most eminent public sector science and technology institutes as well as a range of private sector biotechnology firms that include relatively recent establishments such as Stempeutics Research, a stem cell firm that claims to develop therapeutic products using adult stem cells. Stempeutics Research was granted "limited approval" by the DCGI, in 2016, for marketing India's

first " 'off-the- shelf' " allogenic, bone marrow stem cell based product for a vascular condition known as Critical Limb Ischemia that occurs as the result of Buerger's disease[9] (Stempeutics Research 2016). The product was an outcome of a joint partnership between Stempeutics and CIPLA, India's well-known generic drug manufacturer (Stempeutics Research 2016).

According to 2003 data, healthcare companies accounted for 25 percent of biotechnology firms in Bengaluru (Chaturvedi 2005). Among these was India's leading biotechnology firm Biocon whose business grew significantly in the 1990s, a period when the health biotechnology sector witnessed an expansion in general. Industry-friendly policies from the 1990s have been crucial in shaping future directions of private sector health R&D. With India's entry into the World Trade Organisation (WTO) in 1995, the country witnessed an expansion of its health biotechnology industry that benefited from the liberalisation of trade in goods and services and easier movements of people, commodities and investments from abroad (Arora 2005). According to Salter, the country's membership with the WTO had "reassured" foreign investors looking to expand their business to India (Salter 2009:65). Multinational firms based in the U.S., for example, increased their R&D investments in India from 5 to 80 million dollars between the years 1994 and 2002 (Salter 2009). The benefits from India entering WTO, however, also brought new pressures for profit generation among Indian biotech firms. With challenges of global markets and international competitors in the absence of "risk capital", many health biotechnology firms such as Biocon, Reliance Life Sciences, Shanta Biotechnics and Nicholas Piramal adopted different innovative models for further growth and revenue generation (Arora 2005; Frew *et al* 2007:411). The relatively recent entry of UCB banking is a significant source of revenue for some biotech companies such as Reliance Life Sciences that has a public and private cord blood bank (Reliance Life Sciences 2009; ABLE 2012). Reliance Life Sciences is described in the ABLE report as one of India's "home grown" biotech companies situated "at the forefront in the development of stem cell products and therapies" (ABLE 2012:34). From clinicians of this study we know that the industry that included a corporate enterprise owning a CB bank, were also involved in covert networks of stem cell provision. Stem cell providers narrated how biotech laboratories brought their cell processing technologies to the clinician's doorstep, making the covert provision of stem cell

[9] Buerger's disease is a vascular disorder that affects arteries and veins in the arms and legs causing tissue damage, that in some cases leads to amputation. Cigarette smokers and tobacco chewers are at a higher risk of being affected (Centers for Disease Control and Prevention 2017).

treatments highly feasible. In one case the provider sourced stem cells from a firm's bank and in another instance the cells were sent to the firm for processing.

The other older and more significant source of revenue generation for biotechnology companies today is contract services of which clinical trials and or "drug discovery" is a major component (Frew *et al* 2007:406). Collaborations or partnerships, a common phenomenon in the sector, involve contract research, contract manufacturing and also collaborative R&D arrangements (Arora 2005). Two major macro policy initiatives affected by global developments and national laws were the major reasons for the emergence of India's clinical research industry and the growth of its health biotechnology sector in general. First, India under WTO signed the TRIPS or Trade in Intellectual Property Rights Agreement in 1995 and was given until 2005 to fully comply with the new rules. The TRIPS agreement meant that India had to recognise product patents in medicines and harmonise its intellectual property laws with international standards. This policy shift that threatened India's indigenous generic drug industry producing relatively low-priced, unpatented drugs was simultaneously beneficial for the global pharmaceutical industry[10] that by the 1990s, had begun to outsource drug development to relatively-low cost locations in Latin America, Eastern Europe, Asia and Africa (Thiers, Sinskey and Berndt 2008; Petryna 2009). Faced with patent expiries of hugely profitable brand name drugs and a lack of innovation in the drug pipeline, the global drug industry claiming high infrastructural costs that included patient recruitment in traditional clinical trials sites in North America, Western Europe and Oceania, expanded its operations outside these regions (Thiers, Sinskey and Berndt 2008; Petryna 2009). India was added to the list of attractive countries in 2005 when it changed its drug development laws that significantly expanded the scope and nature of clinical trials in the country, and also increased opportunities for revenue generation from outsourcing activities. In 2005, when India acquired the designation of a TRIPS-compliant state, the country's Drugs and Cosmetics Act (1940), the main statute that oversees the manufacture and distribution of drugs, was also amended. The new rules allowed clinical trial operators to test a new drug substance in India concurrently with other trials run outside the country. Prior to these changes, clinical trials for new drugs of foreign origin were permitted only if the later phase had already been conducted elsewhere.

[10] Today, about 60 percent of the global pharmaceutical market share belongs to the drug industry operating in the U.S. that includes both European and American drug companies. (Petryna 2009:208).

For example, a phase II[11] trial for a drug of foreign origin was only permitted if the confirmatory or phase III trial had taken place outside. This rule prevented the country's population from becoming first line trial subjects and was therefore an important safeguard in the law (Nundy and Gulhati 2005). With significant changes to clinical research in the country and globally, India offered key services for clinical trials — healthcare infrastructure with "state-of-the-art facilities" (Jayaraman 2004:440), well trained English-speaking physician-investigators and patients, all at significantly reduced costs "by as much as 60 percent" than what sponsors would pay in the West (Nundy and Gulhati 2005:1634). Trial subjects available in large numbers were a prized attraction leveraged by key players in India's clinical trial industry that included the state and the medical profession. Based on CenterWatch estimates, less than five percent of the U.S. population participates in clinical trials (Drennan 2008). "Inefficiency" in selecting patients for trials is believed to cause "90 percent of delays" faced by the global pharmaceutical industry, and barriers to recruiting are compounded by the unavailability of the right kind of patient (Bernard 2002:8). Populations in the developed world are "using too many drugs" making them "treatment" "saturated" and hence unsuitable for trials due to the likelihood of "drug-drug interactions" that can affect accurate assessment of outcomes (Petryna 2005:1-3). India, on the other hand, has a "genetically diverse population of more than 1 billion people who have not been exposed to many medications but have myriad diseases, ranging from tropical infections to degenerative disorders" (Nundy and Gulhati 2005:1634). These are known as "treatment-naïve" subjects and are mostly India's poor who have limited access to healthcare (Petryna 2005:3). According to Kapil Sibal, a former minister of science and technology, India's "large diverse heterogeneous human population" is one of our "natural strengths" which, in his opinion, could "help" take the biotechnology "sector forward" (DBT, GOI 2006).

Dr. F, the vascular surgeon, held similar views to that of the minister mentioned above. India "can take a lead" in stem cell science because "we have lot of patients, lot of data" and also a "lot of need", the clinician said at a conference in regenerative medicine (SRMTE 2013). Access to large numbers of trial subjects or patients implied greater potential for acquiring clinically significant data. The Director of the patient organisation for MD claimed that he could easily access trial subjects. "If you

[11] A Phase II clinical trial is conducted to evaluate a drug's efficacy, its effective dosage range and further investigate its safety in human beings. The Phase III trial is conducted to confirm the safety and efficacy information of the drug acquired from earlier phases and to obtain additional information of effectiveness for specific indications. It uses trial subjects in much larger numbers—hundreds to several thousand—compared to the earlier phases (Levine 1988; Angel 2004).

want thousands I can give thousands", he said (Interviewed 27.11.2014). Diabetes specialist Dr. D explained that "unless and until we don't have sufficient data with us we cannot say that we have totally successfully done this treatment" (Interviewed 6.6.2014). The clinician provided stem cell treatment to six Type 1 diabetic patients, three of them children, using autologous bone marrow stem cells. He described his stem cell practice as research even though the treatment did not constitute a controlled, authorised study. Nevertheless, research data when working with clinical uncertainty was a valuable possession for the clinician as it meant having the opportunity to compete with diabetes research in India and the world over. "Just for that I want to do this study", Dr. D stated and expressed a desire to visit conferences where: "I will go there with my data, I will show them that this is the original… that my data is the reality, whatever your telling its not true" (Interviewed 6.6.2014).

The clinician also had ambitious plans for genetic research but for a practitioner who worked in a charitable hospital with limited funds, Dr. D's journey was a lone one. The global pharmaceutical industry is only a "money-making industry" he argued, promoting its own monopolies in drug development whereas the government, he believed, would not support medical professionals like him. In the clinician's opinion, the system primarily functioned to prevent people from working on a "good thing" and that "leads to too much frustration" (Interviewed 6.6.2014). Dr. D's was not the only disgruntled voice among private practitioners. In Dr. E's opinion, clinician's like him who are interested in research should be encouraged by the state. He expressed frustration at the divide between the private and public in health research and the government's partisan approach and blatant preference for corporate hospitals. "Everything is going into corporate hands", Dr. E complained (Interviewed 26.4.2014).

The narratives of these individual clinicians that revealed their unsupported aspirations for research, also manifest professional tensions between clinicians and researchers that prevail due to the dominance of the latter in controlling the direction of translational research (Martin, Brown and Kraft 2008). The recognition that specialists like Dr. D demanded for their experimental stem cell practice was unlike Bharadwaj's and Glasner's argument for the need to develop an unconventional paradigm or alternate space for unregulated treatment practices (see literature review). Medical professionals like Dr. D and Dr. E demonstrated the need to secure a place within existing state frameworks and niche areas of biomedicine, driven by both global developments and supported by internal policies. Dr. E claimed to have a PhD, which gave him the additional qualification of clinician-scientist/researcher,

considered a " 'rare breed' ", the world over (Lemoine 2008:12 cited in Wilson-Kovacs and Hauskeller 2012:500). This professional category was created for the body of practitioners straddling both "research and therapy" (Wilson-Kovacs and Hauskeller 2012:497). The need for clinician-scientists and the problem of their limited numbers was recognised by several countries when developments in regenerative medicine included translational research as a predominant component. The U.K. for example introduced programmes in the 1980s to encourage clinicians to follow "research careers" but the fledgling professional category was encumbered by its inability to pursue research without neglecting clinical duties (Wilson-Kovacs and Hauskeller 2012:499). "If you're seeing a hundred patients a day there's no way in which you have time for the kind of reflective and contemplative work that is required for doing research", explained Scientist A in the context of India (Interviewed 6.12.2013). There are, therefore, "structural problems" to be overcome, according to the scientist, who believed that the responsibility to "grow this cadre of people" lies with the Medical Council of India that should allow "protected time for research" and find ways to increase communication "between basic research and medical application" (Interviewed 6.12.2013). According to Scientist A, understanding the underlying or basic mechanisms of an intervention is not always necessary for a medical practitioner if a well-designed study has proven statistical significance for clinical use. However, a clinician who is ignorant of the "reason why a particular treatment or modality worked" will be eventually hampered in his or her ability to use a "new set of applications" based on "new knowledge", the scientist argued further (Interviewed 6.12.2013).

A liver specialist, Dr. G, who practiced at a trust hospital, expressed the dilemma of the clinician-scientist/researcher paradigm or rather the lack of it, from the perspective of a medical practitioner. "I have excellent ideas" for stem cell research, he proclaimed, but the mechanisms by which stem cells regenerate the liver is still a mystery to clinicians and it is the role of basic scientists to tell the practitioner how to "track" stem cells in the liver (Interviewed 6.10.2013). The clinician had conducted a pilot study to assess the "feasibility" and "safety" of "mobilising" haematopoietic stem cells or HSCs in the body by stimulating the bone marrow, using an existing technology[12]. In patients who met certain criteria, the cells were isolated from the

[12] The technology is known as GCSF - Granulocyte Colony Stimulating Factor. It is a kind of growth protein injected into the body to enhance differentiation of blood forming stem cells in the bone marrow and coax them into the blood stream. The treatment is usually meant for cancer patients before a stem cell transplant or after chemotherapy in order for those

blood by a process called “apheresis” and then infused back again via the hepatic artery. Among the ten patients with end stage liver disease who participated in this study, six survived. With regard to these positive results, Dr. G made an important admission. It was difficult to know whether survival rates could be attributed to stem cells because “nobody knows what is the fate of these stem cells”, he stated (Interviewed 6.10.2013). The clinician, therefore, strongly believed that India’s success in biotechnological innovation lies in tackling the problem at its roots: “first” by ensuring “very good basic science” and second, in making strides to “bridge the gap between clinicians and basic scientists” (Interviewed 6.10.2013).

According to Wilson-Kovacs and Hauskeller, the growth of regenerative medicine as a major area for translational research and the “pressures” to use stem cells in treatments has provided clinician-scientists with a “renewed platform for their professional legitimisation” (Wilson-Kovacs and Hauskeller 2012:497). In the process, the RCT has become a convenient tool by which clinician-scientists experimenting with stem cells have asserted their relevance, demonstrated their expertise and also justified their support for the contentious issue of translational medicine (Wilson-Kovacs and Hauskeller 2012). The arguments of these clinicians find support in the history of clinical medicine that makes apparent how “the most successful sort of problem solving has come from clinician researchers in the West, where they’re actually seeing the practical problems they face in their day-to-day lives”, stated Scientist A (Interviewed 6.12.2013). The history of bone marrow transplantation is a case in point. In 1957, the first clinical trial using the transplantation method to treat cancer was conducted without any knowledge of the HSC or how it functioned (Martin, Brown and Kraft 2008). Martin and others argued that this example in health research contradicted the linear model of innovation for it proved “how the bench is far from being ahead of the bedside” and the “bench-to-bedside” approach should not be the only method by which to investigate the fundamental workings of stem cells (Martin, Brown and Kraft 2008:30,38). There are other more recent examples from different biological fields, such as cell immunity, that have witnessed innovation occurring in the reverse mode or where clinical experience was transferred to the laboratory (Hostiuc *et al* 2016). If the treatment produces results, that is all that matters to the clinician who is “always going to be saying I don’t really care how it works…and that's true for a lot of medicine”, stated Scientist A (Interviewed 6.12.2013).

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particular stem cells to produce more white blood cells that may have been affected during cancer treatment (Cancer Research UK 2014).

Critical voices from within the medical profession in the West have questioned the safety and validity of clinical trials using stem cells and the speed at which stem cell research was progressing into the clinical trial stage (Wilson-Kovacs and Hauskeller 2012:500). For instance, findings from RCTs that used autologous stem cells for heart patients showed results that might have statistical relevance but the "mid-term" benefits of the intervention in patients was uncertain (Wilson-Kovacs and Hauskeller 2012:500). With the emergence of a globalised clinical trial industry worth billions of dollars[13] and the large stakes involved for patent holders, the tendency of sponsors to prematurely over emphasise the clinical utility of basic scientific knowledge is not an unfounded fear among critics. The recent 2017 "national guidelines for stem cell research" of the ICMR and DBT "define stem cells and their derivatives" as drugs thereby recommending stem cell provision in India only in the form of clinical trials (ICMR and DBT, GOI 2017:13). There have been other regulatory initiatives to define stem cells as drugs, discussed in more detail in the next section, which could prove more problematic in the context of unregulated stem cell treatments. In other words, the inclusion of stem cells into the ambit of the clinical trial in India is argued here as a problem since clinical trials have become easy to conduct and new regulations are being used to serve the interests of providers rather than patients. In India today, hospitals across the country including those in small towns offer their services for clinical trials. For smaller, cash strapped establishments, running a clinical trial for a foreign sponsor could mean an easy source of revenue, with patient benefits a secondary consideration (Kahn 2006). The increase in the number of clinical trials in India after 2005 was simultaneous with a stronger presence of the drug industry in clinical trial sponsorship. Prior to 2006 there were 29 industry sponsors of clinical trials, with the number having increased to 350 pharmaceutical companies in 2009 (Ravindran and Nikarge 2010). According to Scientist A, the pressure for product development is "good from one perspective, which is that industry is interested…in basic science" but "the danger always is that you end up with" a low quality product and, therefore, "one needs to be doubly careful" (Interviewed 6.12.2013). The dubious origins and quality of marketable products is not the only concern in India, and the kind of interventions chosen for trials also need scrutiny. The increase in the number of clinical trials in India after 2005 did not necessarily indicate scientific research that was relevant to the country's public health burden. An analysis of India's clinical trial registry (CTRI) in June 2010 for the types of interventions tested,

[13] According to CenterWatch estimates, the global clinical trial market will be worth 64 billion $ by 2020. By this time three-fourths of all clinical trials will also most likely be conducted by Contract Research Organisations (CenterWatch Online 2017).

revealed a preference for those conditions that were lucrative in pharmaceutical markets of advanced economies. For instance, only 1.48 percent of the total number of registered trials on CTRI or 16 of 1078 trials, dealt with respiratory infections and only 0.6 percent were TB studies compared to 13.4 percent of trials dedicated to cancer which is a greater public health problem in the West than for India that has a high prevalence of infectious diseases (Ravindran and Ingle 2010).

According to Lofgren and Benner, globalising clinical trial operations in India has resulted in an industry built on a business model of service provision (Lofgren and Benner 2010:170). In 2010, India's contract research industry was valued at 1.5 billion U.S. dollars with more than half the country's contract research services found in clinical trials (Joseph 2016). Since India's outsourcing sector for global R&D projects has proven more feasible and realisable than product innovation, the "language of innovation and entrepreneurialism" that justified TRIPS was deceptive, Lofgren and Benner argued (Lofgren and Benner 2010:170). Dr. D held similar views on the state of scientific research in the country. Despite "having very good research institutes" India does not have a single patent in diabetes, he said (Interviewed 6.6.2014). Patent filings are major criteria by which a nation's scientific strength is measured and India lags behind other Asian countries in the number of patent filings within and outside the country. In 2004, India's ranking in resident patent filings per million dollars of expenditure in R&D was thirtieth in the world compared to China that was ranked twelfth and South Korea first (Salter *et al* 2007). In Dr. D's opinion, the lack of local innovation stemmed from national apathy towards original research and the assumption of India's role as a "consumer" of "information" produced outside, rather than an "originator" (Interviewed 6.6.2014).

Biotechnology companies and or generic drug manufactures in India have different kinds of collaborative arrangements with multinational firms that include in-licensing agreements which allow an Indian drug company to market a product developed outside or produce a drug locally for a foreign company. The clinical trial, hence, becomes central to the current business framework of drug development as a new drug or interventional product cannot be developed without testing it on humans and neither can it be sold in India without a phase III clinical trial. According to Sunder Rajan, the "Indian pharmaceutical industry has", thus, "itself served as a spur to the CRO[14] [Contract Research Organisation] sector", a major player in clinical trial

[14] CROs offer services to trial sponsors that include trial site management, data management, clinical trial design, medical writing, recruiting trial subjects and investigators.

operations (Sunder Rajan 2007:71). Although India's share in the global clinical trial industry is minimal,[15] several old and new actors are involved in clinical trial operations. Efforts continue to be made by the state and industry to increase India's participation in global R&D and to protect the country's reputation of having lax regulatory and ethical standards. A vast institutional network has developed that comprises different bodies assigned various roles that cover the ethical, scientific and regulatory concerns of the clinical trial process. Apart from the CRO, the industry's representative, the DCGI has emerged as a powerful state authority. It is the main licensing body for drugs and vaccines, and any clinical trial conducted for marketing products needs its approval. According to Sunder Rajan, the DCGI was a "fairly peripheral" body within India's regulatory framework but with the emergence of the clinical trial industry it "is now in the process of recreating itself as a serious agenda-setting organization" along with the DBT (Sunder Rajan 2007:71). In addition to these bodies, the institutional ethics committee (IEC) is assigned the task of an ethics review of research protocols, a legal requirement for conducting clinical trials.

These developments in clinical research have only facilitated experimental stem cell treatments rather than strengthened oversight in human subject experimentation. Restricting stem cell provision to clinical trials as a measure to prevent unwarranted stem cell experimentation provided the medical profession with a new and alternative platform to legitmise stem cell practices. Arguing on similar lines to critics in the West, the clinical trial in India cannot be excluded from the discussion on normalisation of experimental stem cell treatments. The following section discusses how regulations and guidelines for clinical research were used to the benefit of clinically unproven stem cell provision.

3. India's clinical trial industry: a pathway for normalisation of stem cell experimentation

The ICMR's and DBT's national guidelines for stem cell research omitted the term "treatment" from the 2013 (and subsequently 2017) document that was present in the title of the older version. This revision implied the unequivocal status of stem cells as experimental interventions (except established hematopoietic uses) to be used only for research purposes (ICMR and DBT, GOI 2013). The document that provides only guidelines to the medical profession was, nevertheless, the state's attempt to curb growing reports of unethical practices in medical experimentation and moreover

[15] Data from 2007 to 2011 showed that only 2.7 percent of registered trials were from India, the lowest figure across seven nations (Selvarajan *et al* 2013).

protect India's global reputation of a nation where rules can be easily circumvented. In 2013, the Central Drugs Standard Control Organisation (CDSCO) published a "guidance document for regulatory approvals of stem cell and cell based products". This document that defines stem cells as "new drugs" was based on the recommendations of a "high powered committee", set up under the aegis of the Ministry of Health and Family Welfare in order to "suggest a road map for regulation of stem cells" (CDSCO, GOI, 2013:2,13). This modification[16] was suggested in order to exert greater pressure on clinicians to follow existing rules of drug development as currently there is "no system by which…a clinic or a hospital or any particular doctor can be scrutinised for papers" stated a member of the high powered committee (Interviewed 14.2.2014). This member, also a scientist, gave reasons for the medical profession's easy engagement with experimentation that has little to do with external oversight:

> Whatever happens between a doctor and patient is considered not questionable…in medical ethics…so they [doctors] just feel that they're doing their medical responsibility…they're to some extent removing the symptoms and after that it's for the patient to figure out what to do… I mean they will just say that it is the best thing they think that can be done. (Interviewed 14.2. 2014)

An attempt to resolve these structural issues in medicine appeared in the form of bioethics, in the 1980s, when the need for a "new approach" to assess the medical profession more objectively was recognised as necessary (Wilson 2011:121). Bioethics developed as a substitute for medical ethics that had failed in assuaging fears among the public and politicians of the possible harmful consequences of new and unknown medical technologies (Jasonoff 2005). The U.S. was among the first countries to formally recognise the importance of an ethics review of clinical research that was not entirely dependent on the judgment of the physician-investigator but involved external oversight mechanisms (Levine 1988). In 1966, an ethics review was made a federal policy in the U.S. and the formation of ethics review boards that would perform the task were eventually institutionalised in the country's laws on medical research[17] (Levine 1988). These bodies were later integrated into globally

[16] In 2013, an amendment to the Drugs and Cosmetics Act was "introduced in the Rajya Sabha". This amendment had a " 'sub-clause' " regarding " 'new drugs' " that included " "all vaccines…living modified organisms…stem cells, gene therapeutic products and xenografts" (Department of Health, GOI 2013:3). Later in 2016, a government press release stated the "withdrawal" of the amended bill (Press Information Bureau, GOI 2016).

[17] The Surgeon General of the U.S. Public Health Service (USPHS) declared the first federal policy for the protection of research subjects in 1966. The policy stated that all grantees of the

standardised ethical procedures for conducting research that were also adopted by India. The IEC in India is a multidisciplinary, voluntary body, comprising medical and non-medical members selected from within and outside the concerned institution or hospital. The 2005 amendment (Schedule Y) to the country's Drugs and Cosmetics Rules, 1945, mentions the IEC as the main body responsible for an ethical assessment of a clinical trial protocol (Department of Health, GOI 2010). The role and function of IECs that are drawn directly from international rules are described in ICMRs "ethical guidelines for biomedical research on human participants" (ICMR, GOI 2006). These guidelines were harmonised with globally accepted ethical frameworks for clinical research provided by bodies such as CIOMS or the Council of International Organizations of Medical Sciences (CIOMS 2002; ICMR, GOI 2006). First published by the ICMR in 2001 and later updated in 2006, the guidelines were revised with the intention of adding new modes of protection for human subjects as "advances" in biomedical science posed "new ethical challenges" for regulators and researchers (ICMR, GOI 2006:1). Areas such as cord blood banking and stem cell research were added to the 2006 edition, and in 2007 the ICMR together with the DBT formulated national guidelines specifically for "stem cell research and therapy" that were updated in 2013 and 2017 as "national guidelines for stem cell research" (ICMR and DBT 2017).

Bioethical principles in research using human subjects are meant to function as an investigator's moral compass, ensuring that the welfare of human participants remains on the forefront of the research process. The role of the IEC in India's bio-economy, that includes undisclosed operations of sourcing, manipulation and consumption of biological material, can be of utmost significance. Inherent risks of clinical research and already embedded structural imbalances between patient, investigator, sponsor and institution only further compound new concerns of review committees in the context of emerging medical interventions. Yet, the ethics review board in India and the world over is plagued with systemic and functional problems and has been critiqued, for example, in the U.K., for performing "purely window-

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USPHS will not be given permission to undertake clinical research unless the investigator's application was reviewed for the methods used to obtain informed consent, the risks and benefits of research and the overall rights and welfare of research subjects (Levine 1988). The 1966 policy statement was the outcome of immense pressure on the U.S. Congress to initiate legislation for human subject protection in the aftermath of wide scale revelations about human subject abuse in clinical research. One of the most influential pieces of writing on unethical human experimentation that stressed the urgency for state intervention was an article published by Henry K. Beecher in the *New England Journal of Medicine*, in 1966, citing 22 examples of unethical studies conducted in the U.S. (Beecher 1966).

dressing exercises" rather than ensuring the interests of the human subject (Allen and Waters 1983:64). Global literature on IECs indicates a host of problems faced by the ethical regulator in its daily functioning (Levine 2001; De Vries and Forsberg 2002). Racial and professional bias was found to be prevalent in these bodies that favoured white members and medical experts (De Vries and Forsberg 2002). In addition, heavy workloads in the absence of adequate infrastructural support for reviewing and monitoring trials were among the major barriers to an efficient ethics review (Levine 2001; De Vries and Forsberg 2002). The IECs of India, having thus adopted an already flawed oversight mechanism are not surprisingly faced with similar challenges to those in the West, and have come under increasing criticism for functioning as "secret societies unaccountable to the public" (Jesani 2009:63). The committees are set up with relative ease and member selection is arbitrary based on personal networks and old professional affiliations. The members are insufficiently trained to cope with large numbers of protocols and any ethical dilemmas that may arise. With medical or scientific members dominating committee deliberations, the final decisions taken are often skewed in favour of technical outcomes and institutional concerns rather than subject interests. Moreover, IECs under pressure to expedite the review process rarely have the time or wherewithal to visit clinical trial sites and or engage with trial subjects. The faster an ethics review is completed the shorter is the wait for investigators and sponsors who have to proceed to the next stage of acquiring technical approvals from the drugs controller. With these external agendas and internal functional limitations, the ethics that the IEC is capable of ensuring is essentially reduced to desk reviews of mainly informed consent procedures (Kandhari 2013). The patients at the other end of the procedural spectrum, sign consent forms with little resistance and the physician-investigator completes the consent process with relative ease.

An IVF doctor, for example, interviewed by Glasner and Bharadwaj described how poor patients would " 'jump at the chance and sign any piece of paper…forget informed consent' " if they were offered free treatment in exchange for donating their embryos for stem cell research (Glasner 2009:291). For couples seeking IVF, consenting to donating biological material seemed a negligible concern in light of the other social challenges they encountered daily as a result of infertility. In contexts of unaffordable and unavailable health services, an experimental treatment might even be the only form of medical care for trial subjects. The ethical principle of patient autonomy, which is a guiding premise of informed consent, functions on the understanding that information is an adequate tool for individual agency and

exercising choice. Giving consent (or declining participation) in a study is therefore considered an act of free, non-coerced choice, regardless of the inhibiting circumstances in which subjects live and operate. By using consent forms, the providers of IVF in Glasner and Bharadwaj's study had in essence erased the "debilitating" contexts under which patients "often from poor social strata" sought treatments (Glasner 2009:293). According to Glasner, easily operational "established procedures" like "informed consent" clearly become a "means by which a society can legitimate medical practices involving patients as ethical" (Glasner 2009:293).

In comparison to IVF seeking couples mentioned above, the respondents of this study were from middle-class backgrounds with relatively greater agency to make choices. Most patients and/or caregivers arrived at the clinical site informed with the ability to access financial resources to try new medical options. They were, in other words, autonomous subjects that the informed consent procedure assumes and also constructs in the process. They were in Foucault's description (discussed in more detail in chapter four) "free subjects" whose freedom to give consent had also turned into a form of individual control by oversight procedures (Foucault 1982:790). The patients and/or caregivers may have experienced stem cell experimentation as free agents but they had also undergone treatments in inherently unequal contexts, if not circumscribed by poverty and lack of awareness but by desperation. Like poor subjects, the seekers of stem cell treatments were also challenged by disability and vulnerability in the face of non-medical support and in the absence of practical and realistic medical options. Vivek with MS, for example, forced to give up his professional life as an engineer had become entirely dependent on his family both financially and socially. Unable to renew his driver's license due to disability, Vivek could no longer use his modified car and spent his days confined to his family's home. In another instance, a caregiver could no longer continue his work as an insurance salesman because he had to stay home and take care of his son with MD. In such circumstances, patients and caregivers were willing to take risks and signing procedural documents became inconsequential to the process of seeking treatments. The consent form in this study, therefore, served a similar purpose to the IVF example as it gave credibility to the provider of unproven treatments with the added advantage of winning the trust of the middle class patient as citizen-consumer (Rose and Novas 2005).

Dr. B claimed that the informed consent form given to caregivers at his centre was different from the usual obligatory documentary requirement. He explained why:

> You see a normal informed [consent form] is just a small rubberstamp that only the patient signs. Ours is an 8-page document, which we give to the patient. This is yours to keep…The copy we have is one page but the copy the patient has is 8 pages…everything about we want to do, what can happen, what cannot happen, everything is there. (Interviewed 15.1.2013)

The very origins of bioethics Wilson argued, was not to challenge the "professional paternalism" of medicine but rather to protect its members from "threatening questions about new technologies" (Wilson 2011:122-126). Mr. Moré[18], a patient of independent private practitioner Dr. C, was asked for his signature "in 20-25 places" (Interviewed 6.5.2014). He also agreed to give a video testimony of his overall experience of the treatment (Interviewed 6.5.2014). Mr. Moré had "no problem in saying yes" to an experiment because he said the doctor "gave me faith that something could happen with stem cell therapy, that I will definitely be able to walk in two months" (Interviewed 6.5.2014).

The unencumbered process of consent procedures and ineffective IECs in India has created a situation where the guidelines have facilitated unregulated medical experimentation and arguably made it even easier. Under the guise of ethical requirements and new clinical trial regulations for stem cell research, providers in some instances have continued their stem cell practice. An ethics review and informed consent, together function as the "twin (neoliberal) legitimating mantras", Glasner argued, having produced a "sanitizing effect" on clinical trial regulations (Glasner 2009:285). Dr. E, although claimed to have temporarily stopped providing stem cell treatments since the updated national guidelines were published, did not see this development as a permanent barrier to his practice. The clinician was considering forming an independent ethics committee, and so resuming his stem cell practice was only a matter of time (Interviewed 26.4.2014). Dr. C's claims of providing free treatment in the form of clinical trials were contradicted by his patients such as Mr. Moré who paid 60,000 rupees each for three, bone marrow derived stem cell injections (Interviewed 6.5.2014). In another instance at Dr. C's hospital, a caregiver had paid rupees 1,30,000 for his wife's stem cell treatment and was making arrangements for more funds, amounting to a total of four lakhs that would have been spent. "I'm a farmer…so it's not like you get a salary. I make what we sell", he said (Interviewed 6.5.2014). The patient organisation similarly claimed to provide treatments in clinical trials but there was no indication of regulatory permissions and compliance with the compulsory requirement of an ethics review. Clinical trials are

[18] This interview has been translated from Hindi.

meant to be free of cost but the families associated with the organisation had also paid for experimental stem cell treatments. Dr. C's website laid emphasis on the term "research" giving an impression of stem cell treatment outcomes as results of only clinical trials or research studies (Last viewed 8.12.2016). While the CTRI, an online registry, corroborated Dr. C's claim of registering trials using adult stem cells for various conditions, it was still no indicator of whether any of the trials registered were conducted in accordance with regulatory and ethical requirements (CTRI 2016). From the information given by Dr. C's patient Mr. Moré, we know that the informed consent process was followed but we also know that the clinician charged vast sums of money for the treatment. Providers charging patients did not, it seemed, preclude the application of some ethical prerequisites for clinical research, thus blurring the lines between regulated and unregulated medical practice and confusing priorities of research and treatment.

Bioethics that developed as a necessary interface between science, state and society had in these instances only made experimental practices more " 'socially palatable' " and acceptable to the public (Anon 1983b cited in Wilson 2011:124). In addition to following ethical guidelines, there are also stipulations for stem cell researchers on the different kinds of stem cells used, with varying perceptions of ethical and moral values attached to the cell types. For instance, the use of hESCs for research is a "permissible" area for the ICMR and DBT but there are some components that fall under a "restrictive" category requiring closer "supervision" and "additional" "monitoring" by oversight bodies like the National Apex Committee for Stem Cell Research and Therapy and the IC-SCR or the Institutional Committee for Stem Cell Research (ICMR and DBT, GOI 2017:23). These components include the "creation of human pre-implantation embryos by IVF…with the specific aim of deriving ESC lines for any purpose" (ICMR and DBT, GOI 2017:23). In comparison, the use of adult stem cells in humans is relatively unencumbered by regulatory barriers in India and also falls within the "permitted" area of research with fewer implications for stricter monitoring than studies involving the use of embryos or eggs. In addition to the regulatory bodies mentioned above and the IEC, the CDSCO that is the umbrella body of the DCGI is a key authority for approvals and permissions for stem cell clinical trials. The treatment providers interviewed in this study claimed to have used only adult stem cells that include those from cord blood and bone marrow sources. "We have stayed miles away from" human embryonic stem cells, stated Dr. B, seeming to absolve himself of any potentially controversial situation (Interviewed 15.01.2013). The stem cell trials registered with the CTRI on December 2016 were

also studies that used stem cells from only adult sources (last viewed 21.12.2016). With the ethically problematic and clinically dangerous hESC cell occupying a large part of policy concerns and public interest, the indiscriminate use of the adult stem cell has fallen under the radar. The disadvantages of adult stem cells are well known among the scientific community. Adult cells have limited capacity to self-renew which makes the production of adequate numbers of cells for large-scale clinical use of tissue repair or transplantation currently unfeasible (Interviewed 3.2.2014). Secondly, the adult stem cell is "restricted" in its "lineage" which means that a bone marrow stem cell, for example, has limited ability to produce a "functionally differentiated" cell that could be used for tissue regeneration other than blood or for purposes outside the tissue of its origin (Interviewed 3.2.2014). In some quarters there is great hope for the adult stem cell but the evidence, said Scientist D, is insubstantial and the numbers of clinical trials do not necessarily amount to useful data for therapeutic purposes (Interviewed 3.2.2014). According to Scientist E, the momentous discovery of iPS cells by Yamanaka (see introduction) had introduced an "entire new area of thinking" in adult stem cell research, however, "if you try to create tissues from iPS cells or if you try to put back iPS cells you get completely horrible abnormalities, you get tumors and cancers" (Interviewed 5.2.2014).

The categorisation of stem cells between adult and embryonic, the varying degrees of technical and moral oversight, and the policy response to hESCs in countries like the U.S., has contributed to the general misconception of the use of adult stem cells as always ethical and safe. According to Dr. A, taking consent was not necessary for autologous stem cell treatments. For Dr. B, the position taken by India's guidelines is very clear, "if you have to do stem cell therapy use adult stem cells" (Interviewed 15.01.2013). While clinicians like Dr. B claimed to only use the less problematic adult stem cells, others like Dr. Shroff have openly challenged regulatory authorities by advertising hECS treatments and also claimed to have filed patents in the field (LifeCell 2015). Ethical regulators like the ICMR have no legal standing and current systems for addressing medical malpractice such as the Medical Council of India is itself rife with corruption (Srinivasan 2006; Ravi 2017). Dr. A asserted his professional expertise in the face of incompetent regulatory bodies for stem cell research. The state is "in-charge" of developments in technological innovation, but when the subject of stem cells has to be tackled "all of a sudden" state officials "have no clue…so that is the tragedy with the government", the clinician stated (Interviewed 25.1.2013). Whether current national guidelines that permit stem cell provision only in the form clinical trials will have any impact on unregulated practices in the future, it

is difficult to ascertain. Meanwhile this study makes apparent that clinicians did not take regulatory authorities seriously and in any case they had negotiated their practices around the new clinical trial regime.

Discussed in the previous chapter, the stem cell providers who provided unregulated, paid-for stem cell treatments were trained professionals who practiced within legitimate clinical set ups. For example, Dr. B's centre for disability was listed with the Ministry of Empowerment and Justice and Dr. E occupied a senior position in the regional IMA structure. These were medical professionals who functioned within established systems and even desired recognition and assistance from the state. They used state promoted initiatives and policies to legitimise their practices and in turn, macro level policies have helped build an industry in healthcare and health research that have only been advantageous to stem cell provision. Developments in policy circles to curb unregulated stem cell provision have not been accompanied by changes to solve the systemic crisis faced by existing oversight mechanisms of medical experimentation using human subjects. The wide reporting of ethical violations in clinical trials in the media, in recent years, has exerted pressure on state mechanisms to tighten regulatory controls. An unregulated industry could jeopardise India's efforts to become a serious contender in the global biotechnology industry and thus ethical principles have become important moral registers by which the contradictions of poverty, vulnerability and disability are seemingly resolved. Indeed "morality" is "incorporated as a key factor in economic and political calculations" in state policies, Glasner argued (Glasner 2009:285). Among recent policy recommendations is to strengthen and expand the components of oversight of clinical research by bodies such as ethics committees. This shortsighted move could have dangerous implications for human subject interests as it only gives further power to authorities that are already over burdened and underequipped to carry out their current responsibilities towards the trial subject (Thatte and Marathe 2017).

Arguments for regulation as the key solution to the problem of stem cell practices in India stand on flimsy grounds in light of this study's findings and existing scholarship that looked at how regulations have assisted rather than prevented activities in controversial medical technologies (Basu 2006, Srinivasan 2006). To briefly recapitulate observations from various studies in India and other parts of the world on the implications of regulation: Cohen in the context of illegal trade in organ transplants in India argued that after the establishment of local state bodies like the authorisation committee, "it paradoxically became easier" for clinics to broker deals

between Indian clients and donors (Cohen 2005:81). For Koenig, adherence to the scientific method in the form of randomised clinical trials could begin the process of routinisation of an experimental medical technology rather than prevent it. Jasonoff's comparative study of advanced economies analysed regulations as promoters of normalisation of new medical technologies and for Valenstein, and later Blume and others, there were several compelling reasons for the embedding of new medical technologies that regulations may not resolve. In recent contexts of regenerative medicine, arguments were made about the pressure for translation of research into the clinic causing more harm than good (Wilson-Kovacs and Hauskeller 2012). Authors like Bharadwaj and Ong on the other hand, argued for another kind of ethics to analyse stem cell providers that do not conform to global standards of scientific and bioethical conduct.

Attempts made by India to harmonise stem cell guidelines with that of the West were strategic acts of appeasement to business interests, Bharadwaj and Glasner argued (Bharadwaj and Glasner 2009). Recent reporting of possible new regulations leaves little room for doubt in Bharadwaj and Glasner's observations on state intentions for introducing globally acceptable measures for research oversight. In 2016, *Business Standard* reported the government's intention to introduce further changes to the Drugs and Cosmetics Bill in order to improve regulatory mechanisms for new biotechnologies such as stem cells and regenerative medicine (Patel 2016). The reasons given in the government's statement for reassessing existing laws for these areas was "to facilitate the ease of doing business…and enhancing the quality of" India's products (Patel 2016). With a more innovation friendly environment "spurred" on by favourable government polices, India's biotechnology industry hopes to contribute 100 billion dollars to India's GDP by 2025, the ABLE report stated (ABLE 2012:11, 21). The country today occupies the third position after Australia and China in the number of biotechnology companies in the Asia-Pacific region (Salter *et al* 2007). India's stem cell market in particular was worth 450 million dollars in 2010, and is growing at the rate of 15 percent according to the report (ABLE 2012:34). The optimistic projections for the regenerative medicine industry belie scientist warnings. Mentioned earlier, lay actors experience hope in new or experimental technologies quite differently from experts, "except" perhaps when "contingencies" become obvious over a period of time (Brown and Michael 2003:13). The media has been a familiar and predominant actor in deciding and shaping peoples expectations of a new technology. In the case of reproductive technologies in the U.S., for example, "television news reports and talk shows" played an important role in making these

innovations once understood as “esoteric” and expensive into “commonplace” medical interventions (Becker 2000:12). With the growing commodification of healthcare in India and the Internet expanding its base as an information resource, medical technologies are also new markets for the new media. In the relatively recent cases of cord blood banking and stem cells, the media, old and new, has enhanced “the intensity of promissory communication” that is now an embedded feature of biotech industries worldwide (Morrison and Cornips 2012:262). The following section outlines popular English language, print media reporting on stem cell research and on-line advertising of stem cell treatments. In the context of global reports and specific national initiatives, the section analyses the various modes of presentation of knowledge that different media platforms permit and how these ways of providing information can be misleading rather than useful and informative to the reader or online visitor.

4. Media coverage of stem cell research and treatment in India

The creation of the world’s first hESC line in 1998 was reported widely in the U.S. media (Park 2011). Since Thomson’s announcement, “the cells have become a household word” stated WTN news, an American media firm dedicated to healthcare technology and business reporting (Devitt 2008). The media in India also reported this landmark moment in the history of stem cell research (*TOI* 1999). The excitement generated in the media was understandable then. Thomson and his team had extracted stem cells from a human embryo that in the natural scheme of things would have had a very short life span before it differentiated into the 220 odd cells that comprise the human body (Devitt 2008). Under artificial conditions these cells were able to self-renew, uncontaminated and without becoming specialised cells. The implications of this ability to grow and control a viable source of replicating but unspecialised stem cells in a laboratory dish were enormous for medicine. It meant that a self-renewable cell line could be made available for clinicians to use as and when it was required for differentiation into the desired tissue type.

At this historical juncture of stem cell research, India—as discussed earlier in the chapter—was not unfamiliar with the various benefits of investing in techno-science. On the contrary, the country made global and national news not long after Thomson’s highly popularised event. In 2001 when the U.S. announced new restrictions to hESC research, the BBC described India’s biotechnology industry “as the next big thing to hit the country” after the “software revolution” (Thorold 2001). That same year, Rediff.com, an online news portal reported that Reliance Life

Sciences, the owner of seven of the existing and recognised 64 hESC lines by the U.S. government, was filing of a "provisional patent" with the U.S. patent office (Baburajan K 2001). The *Washington Post* in August 2001 reported how certain sections of the Indian media and scientists interpreted policy changes in the U.S. as an opportunity for stem cell research in the country. "India plans to fill void in stem cell research" was the title of the piece that stated how Indian scientists "are ready to forge ahead" and take "advantage" of the "restrictions" imposed on hESC research by the U.S. government (Lakshmi 2001 para.1). The *Times News Network* of *TOI*, also in August 2001 reported: "Indian stem lines to be part of research" and "an Indian stem line could conceivably…combat disorders such as diabetes and heart conditions that Indians" also suffer from (*TOI* 2001:12). A month later, the same year, *TOI* interviewed scientist M.M Panicker at the National Centre of the Biological Sciences who advised restraint in media reporting of stem cell research in the country (Singh 2001:10). "I'm afraid most of what has appeared in the media is misinformed", he said. According to Panicker, stem cell research in India was "getting undue publicity" for "there are several labs in the world doing much more advanced work in this field", and more significantly a "lot of research is required before many pieces fall into place", he stated (Singh 2001:10).

Mainstream news on stem cells rarely provides the reader with a balanced view of the science. A broad examination of the nature of stem cell reporting in the *TOI* from 2001 until the present reveals how the coverage disproportionately emphasised the potential "promise" of research while subverting its enormous challenges. Titles such as "Hope Cells" (Raaj 2005:9) and "Celling hope" that might attract the reader to the story are misleadingly optimistic (Gomes-Gupta 2005:A3). A short paragraph below the latter title, printed in a larger font, declared how the "potential to find cures for the incurable is immense, yet stem cell research, in particular human embryonic…finds itself shrouded in controversy with its ethical boundaries questioned the world over". This statement gives the impression that ethical issues are the only barriers to success in stem cell research. It is only in the last paragraph of the piece where the facts emerge about the "many more scientific hurdles to overcome" (Gomes-Gupta 2005:A3). Titles of stem cell stories implying imminent cures with factual information found buried in the body of the text that the reader could easily miss or ignore was a recurring theme in the newspaper's narrative format. In another story titled, "Stem cells move closer to clinical reality", the journalist writes about how scientists in the U.S. had for the "first time" managed to grow stem cell lines in culture devoid of "animal products" that were known to "harbour viruses" (*TOI* 2006:31). Developing a

virus-free culture medium was an important achievement but the article failed to state how close or rather how far the science was in proving its clinical utility and safety. In yet another example, in the *TOI*, a human liver grown from stem cells in a laboratory by Japanese scientists is described as a "breakthrough" that "may pave the way for ending critical shortage of donor organs" (Sinha 2013:21). This liver was transplanted into mice where it successfully matured and functioned like any other human liver. "However, clinical trials" of transplanted cells "have presented unsatisfactory results" said the last statement of the article, also failing to mention that positive outcomes in mouse models does not guarantee a replication of results in human beings (Sinha 2013:21).

An initial "surge in hype" about a new technology is necessary to generate interest among investors, policy makers and the public, observed Borup and others (Borup *et al* 2006:290). The authors also find that the early excitement is, however, almost always replaced by "disappointment" (Borup *et al* 2006:290). In a recent piece on stem cells in The *Indian Express*, dated January 18, 2017, an interview with Nobel Prize scientist Yamanaka is titled, "There were great expectations from stem cell research. Here's why it fell short" (*Indian Express* 2017:11). In 2006, Japanese scientist Yamanka proved to the world that adult stem cells could become pluripotent by being reprogrammed into an embryonic like state with the use of just four growth factors. Ethical controversies that had beleaguered hESC scientists for decades seemed to have come to an end with this new and workable alternative cell called the iPS or induced pluripotent stem cell. Yamanka later retracts this claim. "We are still in the early stages", he stated in the interview (*Indian Express* 2017:11). The eminent scientist's retraction did not imply that iPS technology is without any successes but the promise "was overstated" (*Indian Express* 2017:11). The idea that stem cells "Can Be Tailored for Patients MADE TO ORDER", another story title in the *TOI* in 2005 (*TOI* 2005:21) were, thus, "unrealistic" expectations from stem cell research, Yamanaka stated in this interview held over a decade after the iPS cell made waves in the scientific community worldwide (*Indian Express* 2017:11). In terms of therapeutic applications, there are perhaps ten conditions only that could hope to benefit from stem cells, Yamanaka claimed (*Indian Express* 2017).

It remains to be seen how the media reports on stem cell science in the future. So far, voices of reason from the scientific community have largely gone unheeded in the coverage of stem cell research. While there is some reporting in the *TOI*, for example, on "stem cell therapy" having "its limitations", an excessive use of rhetoric based on

hope in the absence of current realities has presented a distorted picture of stem cell research and India's scientific capability (*TOI* 2002:12). According to a story from the *Times News Network*, India will "zoom ahead on the stem cell research highway" and the "architect of this plan" was Dr. Anbumani Ramadoss, a former health minister (*TOI* 2005:8). The journalist was reporting the minister's speech at an international symposium on stem cell research in Mumbai, in 2005. Speaking on the subject, the minister declared that "Indian stem cell research will start showing results in the next two years" but in the same speech while referring to hESC research, Ramadoss also warned the audience: "we cannot rush into it as there are concerns about cancer" (*TOI* 2005:8). This latter statement, a fact that was juxtaposed with the earlier objective of rapid outcomes in stem cell research was contradictory in its message and possibly confusing to the reader who is also informed in the same piece about the government's intention of setting up cord blood banks. Whether these were public or private banks it was not clear and moreover cord blood stem cells were wrongly understood as "the master cells" that "can take shape of any of the 220 functional cells in the body" (*TOI* 2005:8). This description applies to hESCs and not stem cells found in cord blood.

Terms like success, hope, miracles, magic and breakthrough are dominant frames or themes within which the potential of stem cell research is either exaggerated or misrepresented by what Brown called the "miss-selling" of truths (Brown 2005:332). The "breakthrough" metaphor for instance, "serves as one of the most pervasive temporal abstractions for describing key events in science and medicine", observed Brown (Brown 2000:87). Used by both scientists and the media to publicise research and stimulate interest in potential funders, the breakthrough metaphor while beneficial in narrating events is also replete with "ambivalences" that can misdirect public opinion (Brown 2000:87). Brown illustrated the dangers of the common use of this metaphor with the case of Dolly the cloned sheep who was never a clone, it was later "contested" as she was not "exclusively a copy" of just one animal but a product of three sheep[19] (Brown 2000:101). While Dolly's birth was "far from being any ordinary breakthrough" the widely publicised implications for human cloning may have created fear and controversy that was unwarranted and unnecessary, argued Brown (Brown 2000:99,102). The use of terms like breakthrough could therefore undermine or exaggerate already existing uncertainties in the science itself. Similar

[19] Dolly had inherited the genetic features of not only the ewe from whom the adult cell had been derived but also from the egg donor[19]. The third ewe was the surrogate in which the fused egg (adult and donor egg) was inserted (Brown 2000).

to the work of Brown, Van Lente also explored different "language strategies" employed to mobilise support for certain technologies (Van Lente 2000:44). The use of phrases like "technological progress" according to Van Lente, functioned as "ideographs"[20] that were manipulated in certain ways to first create the promise in a technology and then later to justify its use (Van Lente 2000:44-45). One of these strategies, he examined, was to juxtapose a new technology with past technological achievements in order to lend it credibility and value. For example, promoters of the Human Genome Project likened the scientific endeavour to "putting a man on the moon, thereby giving it the same urgency" (Van Lente 2000:46). Similarly, when high-definition television (HDTV) was promoted in the 1990s in the U.S., reports described the new technology in the context of other major film and television innovations in American history even though the specifics of HDTV may have been different to the technologies of previous eras. In this way, Van Lente argued, technological development was understood as a continuum in "the rhetoric" of innovation that should not be "stopped" because to deprive the next generation from the latest technology was to "commit collective suicide" (Van Lente 2000:48). Similar juxtapositions were found in print media coverage on stem cell technologies. "Stem cells are the new age gene" was the title of an article in the *TOI* (*TOI* 2005:6). The focus of the story was India's advancements in scientific research. The text stated how "India scores. Be it in genetic medicine or its molecular equivalent" (*TOI* 2005:6). The fact that genetic medicine has fallen short of its expectations did not appear essential to mention. The significance of the association between genetic research and stem cells, thus, lay in the temporal connections being forged between the two fields and India's place in the grand narrative of scientific progress. Stem cells represented the next step forward along with genetics research, genomics and other biotechnologies of 21st century science (Brown 2000).

These examples show how defining technological development in terms of success and progress was also dependent on the "weight" an ideograph carries" or "how it is "praised" in "relation to other ideographs (Van Lente 2000:48). For instance, the new HDTV was introduced not because black and white television had failed "but because another 'better' technology" had become possible (Van Lente 2000:56). Using these methods, "the present is measured by the yardstick of the technological promise, and found wanting. As a result, the development is self-justifying", Van

[20] Van Lente draws from the work of linguist McGee who defined an ideograph as a "high order abstraction" that "warrants" certain kinds of "behavior and belief" providing individuals with "reasons or excuses" for taking a certain course of action and not another (McGee 1980:15 cited in Van Lente 2000:45).

Lente argued (Van Lente 2000:56). Hence, “if HDTV were not seen as promising, nothing would be at stake” (Van Lente 2000:55). In the case of stem cells, the absence of cures are emphasised and “pioneering studies” or breakthroughs are presented as developments difficult to ignore when hope has been lost for those coping with incurable conditions (*TOI* 2004:3). The meaning of research in this manner of presenting information becomes synonymous with treatment, and the description of both activities in India is often placed in the context of developments outside the country, thus, giving stem cells a global appeal with the added and major attraction of cutting edge science now available at our doorstep. “Stem cell therapy is being used the world over”, stated the subtitle of a piece in the Pune edition of the *TOI*. It was followed by another statement that read: “A charitable hospital in Pune is offering this treatment for the last six months at a reasonable price” (Barde n.d). In the body of the text the head of the hospital is described as somebody who has “performed thousands of free operations across India” and has made stem cell treatment available “at almost 10 percent of the cost” compared to rates in the U.S. (Barde n.d). The terms “charitable”, “price”, and “free” associated with a local hospital were given credibility by being clubbed together with “world” and “stem cell therapy”, portraying an offer of treatment that was hard to resist (Barde n.d.).

The example from the Pune *TOI* directly targets patients seeking cures, a feature commonly found on the Internet rather than the print media. Websites of hospitals and clinics offer stem cell treatments for a range of conditions. For instance, the website of Dr. C’s hospital—called a “stem cell centre”—lists 13 conditions for which stem cell treatments were available (First viewed 11.8.2012). In a more recent viewing of the centre’s updated website, a webpage with the title “Regenerative–Ray of Hope” carried text that described “the discovery of the stem cell” as having “led to a revolution in modern medicine” (Last viewed 8.12.2016). Strategies used to attract patients on-line share other features with the print media. For example, a hospital in Mumbai provided links to stem cell studies conducted worldwide for those diseases that the establishment claimed to treat with stem cells. These were scientific papers most likely incomprehensible to on-line visitors, but the association of new developments in global research with treatment options seemingly added value to both provider and treatment (Petersen and Seear 2011). Written testimonials from patients is another method used to add value to the experimental treatment. These accounts almost always tell the story of progress in the condition treated. On Dr. B’s website, caregivers of children with neurodevelopmental conditions like autism have given written testimonials of the changes they observed in their children following

stem cell treatments. These observations described as “improvement in terms of eye contact”, in “sitting” or “partial head control” might have occurred but there is no means of verifying positive outcomes through systematic methods (Last viewed 23.1.2017). The provision of intense physiotherapy that usually accompanies stem cell treatments and focused attention on the child that is inevitably part of the entire process could have produced beneficial results. “Parents spend so much money, naturally they will spend more time with the child and so it could appear that stem cells have been effective”, stated a special educator (Interviewed 30.10.2013). Caregiver Divya held similar views and gives the family’s perspective: “when you use biomedical treatment you become more hopeful so you spend more time teaching your child different things that otherwise can be difficult to sustain for the caregiver”[21] (Interviewed 3.1.2014).

The overall message of optimism and the production of “information as only a ‘snapshot’ in time” serves to “de-contextualize treatment, reinforcing” its apparent “miraculous qualities”, argued Petersen and Seear (Petersen and Seear 2011:337). In this study, Vivek with MS, on the request of the stem cell agent had spoken to doctors at a hospital in Gurgaon about the improvements he had experienced from the first round of stem cell treatment he received in China. Vivek’s outcomes from the treatment were mentioned on the hospital’s website and included, for example, “100 % bladder control” (Last viewed 11.7.2014). Unknown to the on-line visitor was the fact that the “highest point” for Vivek had occurred six months after he returned from China, following which the benefits had “started tapering off” (Interviewed 26.6.2014).

Another way of portraying positive patient stories on-line was video patient testimonials—a strategy not available to the print media but commonly found on the Internet. The video links on Dr. C’s website, for example, were placed under two categories, “condition before the treatment” and “after” (First viewed 11.8.2012). In the website’s latest version, the videos were situated in a side bar under the title “results of clinical research”, presumably a response to DBT and ICMRs new rules permitting treatments only in the form of clinical trials (Last viewed 8.12.2016). These visual depictions typically show adults or children performing a physiological function that was enabled only after stem cell treatment. According to Brown and Michael, the “performance of suffering and pain” has become an “important representational” tool for both “institutions and individuals” to establish “trust” at a time when “scientific

[21] Translated from Hindi.

authority" in the assessment of risk is increasingly being undermined (Brown and Michael 2002:259-261). In the context of controversial biotechnologies, the authors analysed the realm of the affective, that is the "repertoire of feelings [and] emotions" as playing a significant enough role to become indicators of "authenticity" and, hence, also transforming into a means of establishing "openness and transparency" (Brown and Michael 2002:261). Dr. C's website like several others had an on-line request form for more information on stem cells. The doctor's contact details were also provided with the intention, it appeared, to create an "openness" in communication that Brown and Michael refer to (Brown and Michael 2002:261), and so that "concerns" of visitors or patients "are seen to be addressed" by the provider (Petersen and Seear 2011:341).

Petersen and Seear, in their analyses of on-line advertising strategies of stem cell providers found that websites produced an image of the provider as an amiable facilitator of choice and an accessible avenue for hope. Patients were targeted as consumers provided with a range of easily navigable information with the option of asking questions and making clarifications before making a decision. In this provision of not only choice for on-line visitors but also an opportunity to investigate and explore treatment information, Petersen and Seear described on-line advertising of stem cell treatments as a kind of " 'hopeful care' " (Petersen and Seear 2011:339). The Internet provides information that patients or caregivers will most likely not find in the clinic. For Vivek, for example, reading a blog of an MS sufferer where she recounts her incredible recovery after stem cell treatment "convinced" him to also experiment with stem cells (Interviewed 26.6.2014). Proving facts when the facts themselves were uncertain was not important especially when personal success stories from around the globe were accessible in private spaces. To recall Brown, Moreira and Palladino, the "regimes of hope" have superseded the contending "truth regimes" in how new biotechnologies are received and defined (Brown 2005:332; Moreira and Palladino 2005). Stories of miraculous cures from stem cell treatments also make television news headlines and clinicians are invited to speak about stem cell treatments. On 24th May 2015, Dr. C discussed stem cells on a doctors' show for a Marathi news channel that can now be watched on You Tube. At the end of the programme if viewers wanted more information on stem cells they could contact "Universal Hospital" in Pune at a telephone number that flashes on the screen (Last viewed 20.1.2017). A "stem cells" search on You Tube showed 2,180,000 results on 31 January 2017. On the first page of the search is a video posted of the current Prime Minister "Modi Speaking About Stem Cells" at a private hospital in Ahmedabad,

Gujarat (Last viewed 31.1.2017). In less than four minutes the viewer can watch the nation's leader proclaim India's ancient association with stem cell technology that laboratories in the U.S. have only recently begun to investigate. As evidence to this grandiose declaration, the PM cited a mythological character from the Mahabharata who was born from stem cells (Last viewed 1.2.2017). A few links below Prime Minister Modi's speech was a video in Hindi by Dr. Alok Sharma on stem cell treatments. A well-known neurosurgeon in Mumbai, Sharma claimed "90 percent success rates" with stem cell treatments in conditions like muscular dystrophy. The treatment is "simple", "safe" and "effective" and improvements can be seen in a week, the clinician claimed (Last viewed 31.01.2017).

According to Holborow, the media holds the power to give its audience access to a specific kind of knowledge that through repetition becomes "natural truths and common sense" (Holborow 2007:53). The role of the media in shaping the imagination and identity of entire nations is well documented in literature (Ranganathan 2015). In pre-independence India, state controlled media helped build a nationalist momentum for the freedom struggle and in the decades that followed print media along with film contributed to the construction of a national identity and the developmental ideals of a new nation (Ranganathan 2015). In recent decades, the institution has faced criticism, the world over, for its co-dependence with corporate owners, advertisers and sponsors that exercise insidious control over media reporting strategies (Herman and Chomsky 1988). As a result of India's new liberalisation polices in the 1990s, the Indian media also underwent major changes in its structure and organisation. Private sector involvement and new satellite technology led to the entry of global television companies and a wide range of private channels, giving the media in India a new lease of life in terms of outreach and ownership (Rodrigues 2015). In 2001, for instance, there were 100 channels that viewers could choose from—a massive transformation in television that was earlier synonymous with the single state owned channel Doordarshan (Rodrigues 2015). The media, an outcome of economic reforms itself, produced and encouraged the changing aspirations of a liberalising India, voicing state efforts to define a nation that was not only modern but also globalised in its outlook. By linking quality of life with wider access to "the new choice of commodities" that liberalisation and globalisation had brought to India, the media successfully nurtured a cultural ideal for the country's middle class to aspire towards (Fernandes 2000:614). While this point is elaborated in the following chapter, it is important to mention here that the public's acceptance of ideas promoted by the media has occurred through the institution's everyday usage

of a certain kind of language whereby some ideas get emphasised and others may go unseen and unheard. Language can therefore be a ”bearer of” dominant ideologies and “because it is everywhere in society”, stated Holborow, it can also function as an important indicator of “social change” (Holborow 2007:53). The change for India was the imagination of “nationhood and development” through “meanings” and values assigned to “commodities” that also defined the ideal ways of living through signs and symbols laden with these new meanings advertised in the media (Fernandes 2000:615).

Vocabularies of hope, cures, choice and progress formed the main threads running through media coverage of stem cell research and in the advertising of stem cell treatments. The various representational forms used by providers or other platforms to advertise stem cell treatments adopted both language and imagery not unlike those used to sell other commodities. Reporting breakthroughs generate interests among doctors and patients alike, and treatments are packaged in ways that appear desirable enough for them to be consumed. The “*desire*” for goods, said Baudrillard, is “insatiable because it is founded on a lack” and this experience of “lack” is constantly being compensated by a “succession of objects and needs” (Baudrillard 2001:45). Patients searched for stem cell treatments in the absence of cures and were provided treatment options like other consumers seeking goods and services available in the market in “ever greater quantities in order to fulfill” their “needs and wants” (Sturgeon 2014:406). In the negotiation of a healthcare market, patients and caregivers were encouraged to incorporate values similar to those held in a consumer society that offers individuals a range of products that they can freely “choose or reject” (Sturgeon 2014:406). In this opportunity to independently negotiate information and knowledge in private, public and professional contexts, the “language of hope” in medical technologies was therefore increasingly linked with the language of choice and “empowerment” for the patient or family member (Petersen and Wilkinson 2015:115). Stem cell treatments and cord blood banking were offered to those who could pay high prices and also, seemingly, capitalise on new opportunities offered to them as the means to a happier and healthier life. In other words, the opportunity to hope provided by stem cell technologies was a privilege that belonged mostly to the middle class. As they enacted this hope that their middle class status afforded them, the chances they took with unproven treatments also made them subjects of medical experiments— because of their privilege and not despite it. The following chapter will explore the distinct middle class character of patients and/or caregivers of this study, for whom stem cell treatments were a part of

other practices and options available to them. Analysing patient and caregiver narratives with the support of social theory, the next chapter explores how the freedom to choose also incorporated the process of subject formation. From the normalisation of stem cell experimentation, thus, emerged a new category of experimental subject that was empowered in the choice of having tried the treatment but was also subject to a technology that offered hope when there may be none.

Chapter four

Experimentality and the Making of Consumer-Subjects: 'Hopeful Risk' and the New Middle Class

Introduction

As stem cell treatments get routinely embedded in India's health system and everyday consumption practices, a new experimental population has emerged—the middle class subject. This chapter explores the process of subject formation of patients and/or caregivers who are defined as middle class given their access to material and non-material resources in seeking healthcare, and in the overall circumstances of their lives. Unlike India's poor, historically discriminated against in healthcare access and still the obvious recruits for illegal or legal medical experimentation, the majority of this study's respondents had paid for unproven stem cell treatments in the private sector of their own choosing. In becoming consumer-patients in their negotiation of a healthcare market they were also simultaneously transformed into experimental subjects as they made decisions to experiment with stem cell treatments.

The middle class is an "amorphous social group" defined and understood differently in academic literature and in everyday usage (Fernandes 2011:59). Understandings of the term are usually based on either income or consumption practices but these also remain contested. The middle class in the analysis of Deshpande, for example, is confined to "affluent" groups who are situated at the "top" of "income distribution" calculations, whereas Fernandes broadens the category to include various social and economic groups within the definition of the new middle class (Deshpande 2006:223; Fernandes 2006). For the purposes of this chapter, the understanding of the middle class draws largely from the analysis of Fernandes who ascribed certain basic characteristics to the social category that were also manifest in this study's respondents. To outline the essential features relevant to the discussion here, the new middle class according to Fernandes, implies access to old and new types of economic, cultural and social capital with concomitantly new and existing ways of mobilising such resources after India's economic liberalisation. Secondly, the identity of the new middle class was also built around an idea of a lifestyle gained from practices of consumption. Thirdly, the notion of a middle class life, a product of both state policies and media advertising, manifests itself in the practices of daily living,

through which the group has promoted and retained its privilege (Fernandes and Heller 2006). Fernandes also reminds us that being middle class is not merely about responding to advertising of consumer products but there are other "sociosymbolic" methods by which the group protects and asserts its identity as distinct from the poor (Fernandes 2006:139).

There are several socio-economic groups from both rural and urban India that meet the criteria of India's middle class. Income, caste based inequalities and traditional occupations complicate the categories that are classified, for example, by the National Council of Applied Economic Research (NCAER) as "lower", "lower middle", "middle" "upper middle" and "high", based on household income (Fernandes 2006:84). Fernandes situates these different groups within a hierarchical structure. Among them are proprietors of small business, "merchants and rich farmers" who as the "petty bourgeoisie" emulate the dominant English speaking sections but cannot fully compete with their access to material and cultural capital (Fernandes and Heller 2006:500). This group is followed by another category of the salaried class that owns a degree of "educational capital" but exercises limited "authority over other workers" (Fernandes and Heller 2006:500). Teachers, public and private sector office employees and other lower order professionals occupy this latter category. At the top end of the socio-economic spectrum is the "dominant class" (Fernandes and Heller 2006:500), described by Fernandes as "urban", upwardly mobile, English language educated, "white-collar" professional class (Fernandes 2006:xviii). Having amassed generations of privilege and enjoyed hegemonic control and influence in state and private resources, this section is given the distinction of the dominant group (Fernandes and Heller 2006). For Deshpande, on the other hand, the dominant group is the only section that truly qualifies as India's middle class (Deshpande 2006). Fernandes argued that in India, post liberalisation, the English-speaking middle class asserted its power by excluding other groups from civic life, education and other areas but at the same time it also through strategies of exclusion set a cultural standard that was open for others to follow. This new middle class identity was produced initially through the adoption of new consumption practices facilitated by structural changes to India's economy. By reducing taxes to increase the consumption of goods and lowering import duties to allow more commodities into the market, the government in the 1980s made India's middle class the clear target for its new economic policies (Fernandes 2006). The dominant group embraced its state conferred identity of beneficiary—of India's liberalisation and globalisation policies that claimed to usher in a transformational period for the nation's development. The

gamut of human needs including healthcare and education were increasingly available through the market from this period onwards. The leisure and entertainment industries expanded in the 1990s and the media became a major player in building a new middle class identity and in defining its aspirational goals (Fernandes 2006). In recent times the state that has consistently supported the interests of the middle class, widened the dominant group's influence beyond the areas of business and commerce to include, for instance, the administration of urban spaces (Fernandes 2006). In various ways, therefore, the social group, particularly the dominant section, has been helped by the state in maintaining its distance from other sections and also simultaneously consolidated its own status in the practices of daily living.

Middle class patients of this study entered into experimental subject positions as they (or caregivers) navigated the various options available to them in seeking medical solutions. Access to personal networks, medical professionals, the media and material resources were major structures within which information was sourced and stem cell treatments were accessed. In essence, these individuals may not have encountered stem cell providers if it was not for their middle class backgrounds. They made decisions and took risks that were unusual to the typical experimental subject described as "retrenched workers" (Sunder Rajan 2005:26), economically vulnerable, "tribal" (Sarojni N *et al* 2011:17) lower-caste and "treatment naïve" populations (Petryna 2005:3), who, in other words, are India's poor (Srinivasan 2009). This chapter in analysing the emergence of the middle class experimental subject, thus, adds a new dimension to the dominant discourse on healthcare access and medical experimentation in India. Among the 33 patients and/or caregivers interviewed, there were employees of private sector banks, a former company executive, housewives married to businessmen, a chauffer, a retired lawyer, a schoolteacher, an insurance agent, a former engineer and professor, a fruit farmer, an employee of the electricity board and a retired Brigadier of the Indian army. They lived in cities and towns such as Mumbai, Delhi, Pune, Bikaner, Kolkata, Ahmedabad, Chidambaram, Chandigarh, Gurgaon, Agra and Ahmedabad. A few lived on the outskirts of cities such as two families who lived in neighbouring villages in Theni district, not far from Madurai. Among the 14 patients and/or caregivers visited in their homes, about half lived in gated communities or residential neighbourhoods located in older, elite areas or in relatively new housing complexes. For instance, two respondents lived in single-family bungalows in upmarket colonies of South Delhi and three others lived in high-rise apartments in one of the numerous gated communities in the NCR region of Dwarka, Ghaziabad and Gurgaon.

The patients and/or caregivers did not claim a new middle class identity for themselves, but their distinct middle class character was revealed through their socio-economic backgrounds, their choices and desires, mobility and daily living practices that aligned with their " 'being' " and " 'becoming' middle class" (Srivastava 2015:86). The routes they sought to find stem cell cures and the imaginings that were provoked from the normalisation of this experimentality—of being able to walk or normal speech, acquiring a basic motor skill or just mere survival—unfolded in ways that were similar to the larger aspirational goals of their lives. Their experience of the experimental treatment was embedded within the "material and social conditions" of their existence not only in terms of their ability to negotiate the particulars of the treatment but in how they lived, and in their desire and ability to control and shape what lay ahead for themselves and or for a loved one (Mandel 2002:246).

It is, therefore, argued here that the middle class identity was itself the qualifier for a new consumer-subject status that functioned together with the simultaneous identities of patient and ordinary citizen (Srivastava 2015:xxvii). "We are, relatively speaking, surprisingly ill-informed about the non-poor as a whole", stated Deshpande in his analysis of the term middle class (Deshpande 2006:217). This chapter foregrounds the "non-poor" nature of patients and families of this study, revealing through their narratives how the processes and conditions that assigned them the status of the middle class also drew them into a category that includes the poor, yet distant from them (Deshpande 2006:217).

1. Old and new privilege: a brief historical background of the new middle class with a focus on healthcare access

The new middle class was defined by its practices and participation in the market economy of post-liberalised India. Its identity, shaped by its ability to utilise opportunities and use "occupational skills" in a new economy had also reconfigured its boundaries to include professionals and other social groups that could acquire English education and "cultural capital" because they had "economic capital" (Fernandes and Heller 2006:500). The new middle class was hence different from the traditional elite that derived "its power primarily from property" (Fernandes and Heller 2006:504). Possessing "educational and cultural capital", also a defining feature of the old middle class was tied into land ownership and social standing in society. English education and government jobs in colonial India were usually available to "upper-caste Hindus or high-born Muslims" or those individuals "from

service communities" who were employed by local "rulers" or landowning groups (Fernandes 2006:8). Providing access to educational institutions and state employment were efforts of enculturation by the colonial government that developed a professional cadre among these sections to assist in the daily tasks of governance. Privileges of education and jobs had also allowed them a greater claim on "civic life" in colonial India that included health services (Fernandes 2011:63).

Public health efforts in the form of sanitary measures were confined mainly to cantonments and civil lines with only the Indian elite, a handful of the local population having had access to these racially demarcated services and neighbourhoods (Duggal 2001). Various medical institutions that were established by the colonial government to serve primarily the military also provided services to civilians, largely British and European. These hospitals of modern medicine had separate wards for Europeans and Eurasians (Jeffery 1988 cited in Duggal 2001). The nature of modern medicine and medical care services relative to class position was, thus, a historically embedded feature of modern medicine in India (Duggal 2001). Differential access to healthcare in the country and its public health measures were also influenced by major developments in medicine occurring outside India. With the path-breaking discovery of the germ theory of disease in 1856 that identified a specific cause to a disease, the focus of medical practice turned to individual cures, treatments and medical technologies. As a result, the other equally significant determinants of health such as water and sanitation became secondary to the new biomedical model of health and in overall health planning in India. While Britain had already witnessed its sanitary reforms in the 19th century, the germ theory that changed the overall orientation of healthcare in research, practice and delivery, the world over, also had far-reaching effects in colonial India but without the other public health fundamentals in place. According to Qadeer, with regard to healthcare services outside British military zones, "diagnostic and curative technologies occupied the place of pride" for the colonial state (Qadeer 2011:363). Indigenous systems did not receive state support and neither did the existing cheaper and, albeit, "crude[r]" medical treatments, even though the latter had proven more effective in some cases such as treatments used for small pox in Bengal until the 19th century[1] (Qadeer 2011:365). An over emphasis of curative care and medical technologies also divided the Indian population across socio-economic and regional lines. Hospitals that were mostly

[1] According to Qadeer the promotion of vaccination for small pox in the 19th century proved unsuccessful among the local population as they saw no particular benefit to the "new and foreign method" that had replaced the "popular", cheaper and simpler method of "variolation" or inoculation (Qadeer 2011:365).

state owned were located largely in urban areas at least until 1919, when government reforms brought healthcare to rural India. Apart from government health services, privately managed charitable hospitals established by Indian citizens and missionaries, were among the other forms of health care provision available. British women doctors unable to find work at home were paid to come to India in the 19th century to provide maternity care to Indians in missionary run institutions and dispensaries. The maternity services although viewed as charitable and voluntary were not without their own social hierarchies, with the delivery of services restricted to "urban upper class women" (Qadeer 2011:313). In rural regions on the other hand, where majority of India's poor lived, curative services were limited or non-existent and for instance, the traditional dai system was dismissed as "ignorant" practice rather than valid care that needed to be strengthened as a safe option for women unable to access urban maternity services (Qadeer 2011:312). With "racial" and "urban bias" affecting access to public health institutions, those Indians who could afford the private sector sought the services of independent practitioners of modern medicine (Duggal 2005:23). The earliest available data from 1938 showed a total of 40,000 independent doctors, of which only 23 percent were in the public sector with the rest forming the bulk of private healthcare provision (Duggal 2005). Indian doctors worked as assistants of British surgeons and by the 19th century they could get formally trained in colleges that combined allopathic medicine with indigenous systems. The local language was also used in teaching, particularly in the provinces (Jeffery 1979; Saini 2016). Medical education attempted at this time was therefore more inclusive of class and systems of medicine, but that changed, stated Jeffery, when only western medicine courses in the English language were taught in medical colleges that opened in Calcutta and Bombay in 1835 and a decade later in Madras. The majority of Indian students in these colleges, apart from Europeans and Eurasians, were quite obviously only those from English educated backgrounds — initially "native Christians" and Parsis, later joined by upper caste Brahmins who were not as dominant in medicine in this period as were the other social groups (Jeffery 1979:304; Saini 2016).

Social divisions were thus prevalent not only in service provision but inherent in the evolution of modern medicine in India. Higher education continued to be the privilege of the "urban middle class and rural elite" in the post-colonial period, and the basis for middle class formation and upper caste assertion (Fernandes 2006:21; Deshpande 2006). The privileges acquired in social and administrative spheres in colonial India through bodies such as the Indian Civil Service enhanced the role of

the dominant section in the independence struggle and later in the Nehruvian period increased the group's influence in setting "political-ideological" agendas (Fernandes and Heller 2006:501). The independent state made investments in scientific institutions, colleges and universities at the cost of primary education. An English educated background meant easier access to high positions in the prestigious Indian Administrative Service that replaced the Indian Civil Service. In return for political patronage the middle class was expected to embody the beneficial outcomes of government policies while also in the process become the basis for further legitimisation of state agendas. The group's relationship with the state was thus one historically characterised by co-dependence. According to Fernandes, while the poor were central to the rhetoric of development in the Nehruvian period, the needs of middle class citizens featured in practice and policy and this was made apparent in the 1990s as the class was defined by the changes wrought through globalisation and increased privatisation of the economy including in social sectors like healthcare (Fernandes 2006).

As the meaning of the middle class changed after the 1990s with greater flexibility ascribed to its structure and definition, the dominant section simultaneously held onto to its class privileges "accumulated" over generations in various spheres (Fernandes and Heller 2006:515). English language education in contemporary India is an essential requirement for social mobility and class hierarchies persist in the organisation and structure of India's health system. Medical professionals are usually from the "upper middle class" and at the other end of the organisational hierarchy with some "exceptions" are lower middle class auxiliary nurse midwives, with nurses and technicians falling in-between these two categories (Qadeer 2011:41). The social disparity among health care providers is also reflected in how patients are treated in health care settings, stated Qadeer. If patients are from "common" backgrounds they ironically become insignificant to the process of healthcare delivery, and special attention if given by a provider is more likely an outcome of social standing rather than "disease status" (Qadeer 2011:41). Although there is limited analysis of class-based health indicators, from the scanty evidence available it has been possible to discern certain class patterns in morbidity and mortality data. Qadeer cites 1979 data from the Registrar General that showed " 'levels of living' " having affected IMR or infant mortality rates (Qadeer 2011:35). The records indicated, for instance, that in rural India the IMR was 81 among those populations that used electricity and 121 for those who used oil lamps (Qadeer 2011). In another study cited by Qadeer, the under five children of the land owning Jat community in rural

Punjab had lower morbidity rates in comparison with landless scheduled castes (Qadeer 2011:35). The possession of assets, whether in the form of land or job security, had divided health outcomes even within the same social group, argued Sahu in his study of the Oraon tribal community of Orissa (Sahu 1981; Qadeer 2011:35).

From the 1980s onwards, socio-economic and regional disparities were also embodied in the changing physical landscape of healthcare provision in India. The arrival of the corporate entity in healthcare had accelerated and further entrenched existing social stratifications in India's health system by causing an unequivocal fragmenting even within the private sector. Reform policies were contradictory, stated Ritu Priya, indicating the need to improve primary healthcare but in implementation, encouraged changes to "attract the middle class, [and] suit professional aspirations of a section of medicos and the medical corporate sector" (Ritu Priya 2005:55). Medical professionals like Prathap C. Reddy who were pursuing medical careers abroad, retuned to India just in time to ride the wave of healthcare reform. Introducing the country to its first corporate hospital, Reddy was among the key figures in turning healthcare into a highly profitable business at a scale previously absent in the health system (Lefebvre 2008). The corporate hospital changed the face of healthcare in India quite literally. It created a new ideal standard for hospitals in public image, look and experience for the discerning patient-consumer. Private hospitals of all shapes and sizes advertising multi-specialty services using new equipment and the latest technologies became visible signs of a new India ushered in by reform and a restructured economy (Lefebvre 2008). Although private health care equated with better care is a widely held but highly misunderstood perception of health provision, there were benefits in using private hospitals and clinics for those who could pay. With new therapies, improved surroundings and less crowded waiting rooms, private hospitals could be included in the various "spatial" forms through which the new middle class were offered another way to enact its privilege of choice and option—even in healthcare (Fernandes 2006:138; Lefebvre 2008).

The prefix "new" to India's middle class was, therefore, not a structural departure from the middle class of the pre-liberalisation period, explained Fernandes, and neither did it mean new members being added to the group. Rather, the term implied new features of middle class identity that were shaped and directed by the restructured economy after liberalisation. Economic reforms and the overall exposure of India's markets to global industry, offered new job opportunities in various sectors

such as IT, the entertainment industry, leisure and hospitality, retail, real estate and travel, that appealed to the imagination of the youth as new options were available for socio-economic mobility. These new avenues for employment also introduced legitimised routes for seeking freedom from traditional barriers of class and gender (Fernandes 2006; Gooptu 2009). A study conducted by Gooptu on new subjectivities formed in the retail sector, finds that the employed perceived work opportunities as a means of agency and access to a life "less insular and limited than their parents" (Gooptu 2009:51). For women in particular, working in a shopping mall was an escape from oppressive patriarchal controls as well as a preferred option for enhancing family income (Gooptu 2009). According to Gooptu, these views were held despite low wages incommensurate with long working hours, erratic and arbitrary methods of dismissal and high work pressure for the fear of losing jobs. Moreover, any collective means of representing employee interests were undermined due to an emphasis on individual targets and incentives that demanded the mobilisation of personal skill and reserve as a means of both opportunity and survival (Gooptu 2009).

Shopping malls and entertainment complexes along with wide scale advertising of new consumer goods and luxury homes were all visible signs of a globalised India, offering new objects of human desire. The ways for fulfilling these desires, however, resulted in greater insecurity and uncertainty in the work place that is distinctive to post-liberalisation India (Fernandes 2006). A new work culture emerged creating new demands on individuals, argued Fernandes who described the deployment of "individualized strategies of upward mobility to negotiate the restructured middle class labor market" (Fernandes 2006:130). Among these strategies was acquiring English language skills, an essential requirement for the outsourcing industry as well as in organised retail. English language training institutions have mushroomed across the country capitalising on the need created by the job market. "Prestigious" schools in big cities as well as in smaller towns of India are usually private sector, English medium institutions (Fernandes 2006:133). These establishments that demand high fees and individual donations have exerted greater strain on the resources of lower middle class families for whom the English language is a means of acquiring the social capital necessary for the upward mobility of younger generations (Fernandes 2006).

The use of personal or "informal, privatized strategies" in seeking access to institutions or resources has become regular practice even in healthcare, stated

Fernandes, as the private sector grows to dominate the health system. The nature of networks activated by individuals and the kind of capital mobilised are however varied due to the socio-economic differences within the middle class itself. Lower middle class sections, for example, often have to resort to "gifts and favors" from wealthier families and kinship circles in order to gain entry into private health care facilities even though the public sector would most likely offer the same service for free or at a significantly lower cost than the private sector (Fernandes 2006:135). The healthcare provider has, thus, also developed into a middle class institution constituted by and for the middle class, an issue discussed in greater detail later in the chapter. According to Baru, the emergence of the medical doctor as an entrepreneur, investor or manager of healthcare in India was very much a phenomenon that grew from middle class aspirations of class identity and status (Baru 2006; Baru forthcoming 2018). Baru described how private medical establishments set up by U.S.-educated doctors returning home to a liberalising India, developed into an avenue of upward mobility. These new institutions bore evidence of the personal enterprise and business acumen of these individuals who used social networks and resources in getting what they wanted from the state as they established vast healthcare enterprises (Baru 2006; Baru forthcoming 2018). The non-resident scientific community, mentioned in the previous chapter, was also encouraged by the government to return to work in India. The historical continuity of class-based control in institutional formation and in the social organisation of medicine combined with new developments in healthcare from the 1980s, made the role of personal resources even more significant in medical care. While the importance of networks as pathways of normalisation of stem cell experimentation was described in chapter two, the discussion here looks at the mobilisation of various kinds of capital in the specific context of the middle class character of the respondents that includes doctors who provided the treatment. Accessing stem cell treatment was very much about who the respondents were, the people they knew, what they knew and what they owned.

2. Financial and cultural capital in seeking stem cell treatments

Caregiver Ravi, a chauffeur at a hotel in Mumbai, was helped by his employer to fund his son's stem cell treatment.

> My boss is like a friend", Ravi said, or rather "he's become a friend. He's like my godfather and I have no problem with money, it gets adjusted somehow so that's how it's going. (Interviewed 17.7.2014)

Ravi's son suffered from cerebral ataxia. He had received stem cell treatments twice and his parents were planning a third round. "We'll sell our home, everything" said Ravi, burdened by already stretched resources after he sold a one-room tenement he owned in Mumbai (Interviewed 17.7.2014).

At the other end of the socio-economic spectrum was Mr. Seth, a former company executive who lived in one of south Delhi's expensive neighbourhoods. He received stem cell treatment in Israel, in a clinical trial that he had asked to participate in and also paid for it. Mr. Seth was 69 years old with multiple sclerosis of the primary progressive type. A quadriplegic with his feet covered in cloth bandages, he lived a life confined to a wheel chair. Mr. Seth had two helpers who assisted him in his daily activities that included turning the pages of the morning paper and browsing the Internet. One of them had accompanied him to Israel for the treatment.

Mr. Seth could not "quite remember" how he had "stumbled across the possibility of receiving such therapy" in Israel. He had "a few contacts" there, he said, that helped him with information. He also "checked on the net…the hospital, it was an excellent hospital" and he "wrote to them to ask" if he "could participate in the clinical trial" (Interviewed 28.5.2014). It took some "effort" though, Mr. Seth recalled, to get permission to be included in the trial at a hospital in Jerusalem: "I kept knocking on their door and saying admit me for this clinical trial…they were in no hurry to call an Indian, a 60 plus year old Indian, to their trial". There were two trips involved, one for the extraction of his bone marrow cells and the other for the infusion (Interviewed 28.5.2014).

Two other MS sufferers went abroad for stem cell treatments. Both respondents, a caregiver whose daughter had MS, and Vivek mentioned earlier, visited China on medical visas. The arrangements for their entire trip that included travel, the treatment and accommodation in China was organised through an 'agent'. Apart from these individuals who went abroad for stem cell treatments, other respondents had travelled within the country. Divya, for instance, travelled with her son from Chandigarh to Delhi for stem cell treatment at Dr. B's clinic, while a few other patients and/or caregivers from different parts of the country visited Dr. C in Pune. The three families from Tamil Nadu associated with the patient organisation were sent to Bengaluru for the treatment. Two caregivers lived in rented accommodation in Delhi, mentioned earlier, while Mr. and Mrs. Jain also mentioned in chapter one,

found accommodation in a Jain guesthouse, near the hospital, where their dietary needs could be easily met.

The range of capital deployed in the pursuit of experimental stem cell treatments– both in the form of familiar support structures such as kinship or community and new forms such as 'stem cell agents' and stem cell clinical trials abroad, reaffirmed Fernandes's argument against "homogenized discourses" in defining the middle class as a stable and cohesive social group (Fernandes 2006:135). At the same time, however, access to various kinds of economic and cultural capital also functioned as distinct markers of a collective middle class identity. Deliberate choices and actions as well as unconsciously imbibed activities that were categorised as practices belonging to middle class life have also helped in retaining historical structures of exclusion and privilege. For instance, Dr. B expressed a preference for treating only those patients that were unmistakably middle class, particularly the dominant section:

> I want only English speaking parents who have gone to the net…I'll tell them the links to go. [They] have to be highly educated otherwise we refuse. Highly educated Internet savvy people…they have to read, Google scholar. (Interviewed 15.1.2013)

The clinician's exclusion of those families that did not conform with existing social norms of class privilege was similar to IVF clinics selecting only white, middle class patients, a strategy that Thompson observed in the early days of the technology's use (Thompson 2005). Classifiers of privilege in India such as the English language—among others like gender and caste—that is both a source of social capital and a means to access other types of resources, is what Fernandes described as one of the "classificatory practices" through which the new middle class negotiates its identity in relation to other social groups (Fernandes 2006:xxx). In addition to acquiring English language skills, Fernandes also included a "spatial politics" practiced by the middle class to exclude other groups, in terms of both physical and symbolic distance (Fernandes 2006:138). These practices will be explored in the discussion here with the addition of the exercising of hope as an important practice specific to the making of middle class experimental subjects and one that was deeply integrated in the fundamental process of subject formation.

The enactment of hope or hope as an activity, I argue, is another defining feature of middle class identity, not emphasised enough in current scholarship on the middle class in India. It is important to mention though that hoping is not new in the context

of ill health and disease. Rather, the new element in the arena of hope is the offer—among several others—of new objects, practices and opportunities of hoping in biomedicine. The latest medical technology that offers new ways of hoping is targeted at middle class patients for whom the enactment of hope through the market is increasingly an embedded feature of everyday life. Providers sell the idea of experimental stem cell treatments to the public using new and traditional advertising techniques and the media significantly contributes to the transformation of stem cells into any other object of consumer desire. To recall Koenig's argument: an experimental medical technology being available, in whatever capacity, is enough reason for generating interest, and patients living with debilitating conditions are most vulnerable to hoping for results (Koenig 1986). The readiness of respondents to experiment with stem cells was obvious from their narratives, for hope was all they had. "Hope is what keeps the world alive"[2], stated a mother of an autistic child (Interviewed 26.11.2013). The reason, therefore, to analyse hope in the context of stem cell experimentation was to investigate "what" hope "does" to those seeking stem cell treatments, to borrow from Ahmed, rather than focusing on the meaning of hope for those suffering (Ahmed 2010:2). Ahmed in her examination of happiness argued that the experience was associated with socio-economic privilege and was an outcome of certain acceptable and popular choices that people made. Happiness was, thus, denied to those who did not make those specific choices. The notion of hope here is similarly argued as being tied to the material and social conditions of existence without which hope could not have been exercised and stem cell experimentation would not have occurred.

Although directly marketed like any other good or service, stem cell treatments were also different from other objects of consumption. The treatment, like IVF, instilled in the user a sense of personal power because it gave hope but at the same time it also took away the power due to assumptions of personal "failure", regret and disappointment if the experiment failed (Franklin 1997:135). An understanding of power in the context of hope is therefore important in an analysis of subject formation as patients or caregivers made independent decisions to experiment with stem cell treatments. Being a subject, according to Butler who drew from Foucault, implied a complicated relationship to power due to feelings of attachment or desire towards the source of power. Without desire towards the source of power, used here interchangeably with hope or in close association with it, there could be no "subjection" or the process of subject formation (Butler 1997:2). According to

[2] Translated from Hindi.

Foucault, a subject was anyone "subject to someone else by control and dependence" (Foucault 1982:781). He also defined a subject as constitutive of the "form of power" that "makes subject to" and that which eventually becomes a part of an individual's identity that he or she must embrace through "self-knowledge" which others must also "recognize" (Foucault 1982:781).

Using patient and caregiver narratives the rest of the chapter examines the workings of hope as a source of power that transforms patient-consumers into consumer subjects. The term hope is used synonymously with wishes and fantasies, and stem cells as embodying this hope are understood as objects of desire that must be acquired in order to fulfil hope. The chapter is organised under various themes that explore how hope as a practice also intersects with other signifiers of middle class identity, included among the essential features of middle class subject formation.

3. Hopeful risk and the middle class subject

a) The "compulsion to try"

Hoping for a cure in biotechnology's political economy of hope is not mere wishful thinking, an experience accessible to all human beings, but "an active stance towards the future" (Novas 2006:291; Webb 2013). Hoping, in other words, is not only "an act of the imagination", stated Novas, but is "materialized through a range of social practices" pursued by various actors in the context of medical innovation (Novas 2006:290). Novas derived his understanding of hope from studying the advocacy methods of a patient group, PXE International, whose members shared "collective hopes" of finding cures for a rare genetic disorder (Novas 2006:289). The organisation grew in prominence with the entrepreneurial skills of its "white, middle-class educated" founders who used their intellectual and material resources to gain leveraging power with scientists, clinicians and the state to ensure patient interests in research, diagnosis and disease management (Novas 2006:302). While patient organisations like PXE International intended to represent the entire patient community, their efforts, Novas argued by citing Brown and others, could possibly have alienated the needs of certain social sections that for various structural reasons have been deprived of access to the same resources (Brown, Rappert and Webster 2000; Brown 2003; Novas 2006). The ability to construct the future was therefore "not evenly distributed across social groups" as the ways available to realise a better life is increasingly affected through the market (Novas 2006:29).

Brown and Franklin, discussed in previous chapters, analysed respectively through specific examples of cord blood banking and IVF, how both industrial strategy and state policy had decided the substance of hope as well as its target subjects. To recapitulate some of their arguments as well as that of other scholars, having expectations was reason enough to sell a technology and prove its usefulness, regardless of scientific fact or clinical status. In the overwhelming preference of hope over scientific fact, the state's ideological prescriptions of daily living also shaped the ways in which technologies were used. For example, Franklin situated her analysis of IVF in the Thatcher era that promoted the idea of self-motivated families as key to forming a productive society. Among the popular polices of the Thatcher government that manifest the notion of enterprising citizens defined by their ability to negotiate the market as opposed to beneficiaries of state welfare, was in the area of housing. People were encouraged to buy homes through reduced rates and tax cuts legislated under the Right to Buy Act of 1980. The number of property owners rose significantly by 1990 in the U.K., proving the government's theory of "greater consumer choice" through "greater market freedom" as beneficial for " 'individuals and their families' " (Franklin 1997:77). The private sector also made inroads at this time in the country's National Health Services. Encouraged by tax incentives and the overall policy push for entrepreneurship by the government, clinical establishments offering new reproductive technologies like IVF "fit neatly" into the general policy framework of the 1980s — of possibility, choice and risk as necessary features for success in new markets (Franklin 1997:78).

In India, public debates on surrogacy, in 2016, in the aftermath of the state cabinet passing a bill banning commercial surrogacy, were also framed within the language of choice and an unfair suppression of a woman's right to control her reproductive future. These views were shared on both sides of the class divide even though commercial surrogacy is invariably about unequal class relations. A commissioning party at one end of the socio-economic scale seeks the services of the poor surrogate, for whom hope means different things but its fulfilment is only enabled through options available in the market. Hope was, thus, also privatised in the market for new medical technologies, argued scholars of expectation studies (Martin, Brown and Turner 2008). Since the spaces and methods that facilitate hoping are found increasingly through transactional relationships in healthcare and otherwise, taking risks by challenging existing norms and that which the enactment of hope entails, is thus only possible for those who have greater control over resources.

Respondents of this study, such as Mr. Seth, went abroad for stem cell treatments despite warnings by experts advising him against the treatment. Before making a final decision, Mr. Seth had consulted an eminent professor in Cambridge, in the U.K., whom he described as the "doyen of multiple sclerosis" (Interviewed 28.5.2014). He had also spoken with his doctor at home. There is "no hard evidence…it has to be proved", they told Mr. Seth who did not heed the doctors' warnings. "You wait for your firm conclusion at least let me pursue hope" was his response to the medical practitioners (Interviewed 28.5.2014). The willingness with which Mr. Seth and other individuals subjected themselves or their children to experimental stem cell treatments can be understood as a risk of "vulnerability" undertaken when there were no "reasonable alternatives" (Hayenhjelm 2006:194). **"**Why would I be concerned [about risk], I had my last option", said Mr. Seth who had completely lost mobility in his limbs. "If they'd killed me I'd only been too happy. What's the point they didn't manage to do that even", he said laughing (Interviewed 28.5.2014). Clinicians also assured patients and/or caregivers that adult stem cells posed no risks or "at least it won't get worse" Dr. C had said to his patient, Mr. Moré (Interviewed 6.5.2014). Although not all the respondents were aware of the experimental nature of the treatment or used the term "experimental" or "research" to describe it, most were aware of the uncertainty of treatment outcomes. "As long as there is no harm we can take a chance", they said (Interviewed 9.10.2014). This perceived lack of risk was a recurring theme in the interviews. "What more can be disturbed, what can happen in the future…if there is hope that there can be improvement that's the reason why we are doing it", said Mr. Moré (Interviewed 6.5.2014). Mr. Seth held similar views: "the only thing I felt is a bit of hope…maybe something will come up…maybe I can at least now hold a pencil", he said (Interviewed 28.5.2014).

Taking risks—medical, emotional and financial—for patients and/or caregivers became inseparable from hoping for relief from physical and mental suffering. The suffering they experienced due to intractable diseases and permanent disability did not necessarily translate into medical care despite their class privilege. According to Lock, it cannot be taken for granted that new medical technologies are introduced in society in order to alleviate human suffering or rather patient needs are the only factors considered. The meaning of suffering and the ways to reduce it, she argued, is itself "culturally constructed" thereby complicating its place in the context of healthcare (Lock 1996:209). Advertisements of happy and fulfilled families having undergone IVF or storing cord blood, for example, are not uncommon in urban India. These are expensive medical technologies, with their usage embedded in uncertainty

of outcome and personal anxiety, but the imagery invoked as a result of IVF or CB storage is one of happiness and personal freedom. New biomedical advancements demand that individuals "judge themselves" in order to improve their health and wellbeing, stated Rose (Rose 2001:18). While Rose was referring to individuals making choices in regulated environments of advanced nations, the respondents of this study like Mr. Seth also felt that "the compulsion to try is very high" (Interviewed 28.5.2014). The stem cell treatment offered Mr. Seth no relief or healing but in the end it was the act of trying and using the option available that was important for him. "The fact that nothing came of it is alright", he said, "but I did at least try" and therefore "there's little point of saying its [stem cells] not been too successful here or there or wherever [or] its not yet developed" (Interviewed 28.5.2014).

Franklin similarly described how the feeling of " 'having to try' " was a recurring feature in her interviews with women undergoing IVF (Franklin 1997:170). These individuals were aware of high failure rates but they "felt they *had* to try the procedure" (Franklin 1997:170). Among the factors that made the act of trying necessary for these women was the fear of "regret for not having tried everything" (Franklin 1997:171). The women saw themselves as "doer[s]", as determined individuals who don't "give up easily", stated Franklin, and the act of trying was the affirmation of a decision that turned the "feeling of " 'having to try' " into the "feeling of 'having to choose' IVF" (Franklin 1997:171). In the case of this study, caregiver Mr. Saxena whose child was treated with stem cells at a public hospital expressed a similar dilemma in the act of trying. Initially driven by hope, his decision to try the treatment was later met with disappointment but in retrospect there was comfort in having at least tried:

> If we didn't do it and if we did it and there's no change okay, but if we didn't do, we wouldn't know if it would have been better or worse, it's very difficult to say. (Interviewed 17.5.2014)

In the context of private cord blood banking, Brown described a "moral space" that is "emerging", "where failure to invest now may result in moral recrimination later" (Brown 2005:344). Brown argued how CB banks emotionally manipulated anxious parents into thinking they were doing " 'the right thing' by the future" in storing cord blood even though facts of stem cell science stated otherwise (Brown 2005:342). Another caregiver Martina, whose son with cerebral palsy had been treated with stem cells, felt it was her duty to inform others about the treatment:

> You know I tell everyone really…and I feel so nice doing it…when I meet them [people] on the road…in the station or anywhere buses, trains I go talk to them…first I will ask, your son is a CP child…then I will say, see, I also have a CP child and…I've done a treatment if you're interested… and some say [yes] okay I give [them] the number [of the doctor]. (Interviewed 17.7.2014)

b) Controlling the future

As "new technologies penetrate more and more to the core of our lives", the risks we take in using them are "bound up with the aspiration to control and particularly with the idea of controlling the future", stated Giddens (Giddens 1999:1). For patients and/or caregivers seeking cures from stem cells and the modalities of the treatment were also integrated into the larger framework of planning for the future (Franklin 1997). For instance, Martina described how her goal forming process was not only confined to the private space of the home and family but the clinic itself had helped in defining and organising individual goals:

> When you finish with the stem cells on Saturday they give you a paper and on that [you have to write] for one month, two months what is your goal…and then there is the…one year goal so I have put my one year goal that my son will be standing and cutting a cake on his birthday…that is my goal you know I have that. (Interviewed 17.7.2014)

As a technology "responds to specific desires and hopes" it is also "simultaneously transforming the terms through which new aspirations are imagined" (Franklin 2013:35). The aspirations or expectations from new medical technologies, Brown argued, can be shared by several actors who "collaborate" to control "the future" with "material and social factors" being significant in "the authoring of the imagination" (Brown 2005:344). In the case of caregiver Nita, for example, her experience with stem cell treatment was linked to other ways of improving and enhancing the quality of her autistic son's life and also planning for the future she had envisaged for him. "We…didn't have very good schools here [in India] so we were hoping to get help any which way", said Nita in the context of her son Rishad's treatment with embryonic stem cells at a private clinic in New Delhi (Interviewed 22.4.2014). She lived in Bengaluru during the treatment and later moved to Singapore with her son. It was closer to home than the U.S. or the U.K., she said, and the educational facilities were better abroad. Nita's husband had stayed behind for work, and after her two-year stay in Singapore the entire family shifted to Delhi. They were excited about a new school for autistic children, founded by a couple who had recently returned from the U.S. and were using the skills acquired there to train the school's teachers. "The

reason I decided to move back is because of this school, you know if there's an American involvement and know-how then I can come back home and live with my husband. It's been very tough living away from each other", Nita stated. The personal hardship she experienced had not weakened her resolve but instead had given her greater courage to plan for her son's future:

> I intend to take him by the time he's 13 again abroad maybe to America or England…I haven't heard any fantastic stories of children with…challenges in India whereas in America everyone gets a college education, you hear autistic people are working as architects you know. (Interviewed 22.4.2014)

Nita's son, Rishad, was four years old when he was treated with stem cells for autism. He got a stem cell shot every day for five days a week, in three month stretches over a period of two years. For the first four days of the week the injection was given in his leg and every Friday he got one in his back. Rishad "became toilet trained on his own" during the treatment, although "we didn't know if he was just improving on his own or it was stem cells", Nita recalled. "For five years he's been without any issues…I was doing homeopathy also, I'm not sure if that helped", she said further. Despite the doubt, "I'd love to do stem cells" again, Nita stated (Interviewed 22.4.2014).

c) "Good" technologies

According to Taussig and others, the freedom to choose in a "biomedical" "market-place" transforms biotechnologies "into objects of desire" (Taussig, Rapp and Heath 2005:201). Desire, defined as a wish or a longing for something, could become a potential source of happiness if the object so desired is acquired. Happiness, however, cannot be found just anywhere, Ahmed argued, because it resides in predetermined "places, ideas and behaviours and only if "we do the right thing" by following "the right path" can we get close to it (Ahmed 2010:29). A range of products and services available in the market today tell people how and where happiness can be found, and the conditions that individuals can create in their lives in order to achieve happiness. According to sociologist Veenhoven, happy people usually resided in "economically" advanced nations, were married, belonged to "majority groups", were socially popular, felt "they" were "in control of their lives", and whose "aspirations" were centred on social and moral matters" rather than making money (Veenhoven 1991:16 cited in Ahmed 2010:11). By this definition, happiness like hope, on the "face" of it becomes the right of the privileged (Ahmed 2010:11) as material stability allows certain individuals to make "some life choices and not others" (Ahmed 2010:2). For patients and/or caregivers having access to resources meant leaving no

stone unturned in their search for cures. “I want to live my life knowing I tried everything”, said Divya[3], the mother of an autistic child. “I don’t want to take my last breath feeling that oh god I should have done this, perhaps my son would have improved…and I also don't want to feel that why did I do this” (Interviewed 3.1.2014). Failing to utilise the “right” choices available for happiness renders people neither “worthy” of happiness nor “capable of being happy”, argued Ahmed (Ahmed 2010:13). If you are unhappy and unmarried, for example, she stated, it is not marriage—one of society’s “happiness indicators”—that is understood as faulty but the individual who has made the incorrect choice in not marrying (Ahmed 2010:6). Functioning on the basis of this “science of happiness”, people inadvertently search for happiness in places where it is expected to be “found” even though “happiness is reported as missing” in these very places (Ahmed 2010:7). Caregiver Divya, for example, blamed herself for not overseeing the entire treatment process closely enough and for not being more discerning in her choice of stem cell provider. “I should have gone to Pune where they were separating the cells. Why did I have to get it done in Delhi?” she said, full of self-blame and regret for having made a poor choice (Interviewed 3.1.2014).

Since happiness is identified to be in certain places or practices, those spaces or actions are turned into “good” places or the correct choices, Ahmed stated (Ahmed 2010:6). In promoting happiness, therefore, implies the encouragement of “those ways of living” or very particular choices that are expected to bring happiness (Ahmed 2010:11). Happiness, thus, directs us towards certain objects or practices that acquire “value” as long as the way prescribed to acquire the object is also the “path” where happiness supposedly awaits us (Ahmed 2010:13). In this understanding of happiness, an assumption in the goodness of the path has already been “made” or decided, making expectations of positive outcomes easier to anticipate even before the object is “encountered” (Ahmed 2010:28). As new medical technologies are offered and sold as objects of desire, they are also already assumed to be something good. In this association of the positive with the new, lies the danger of minimising the life-improving potential of other existing measures or possible alternative avenues for therapeutic relief.

A spinal cord surgeon bemoaned the negative consequences that the media’s “undue hype” in reporting stem cells had on established treatments for spinal injuries.

[3] Parts of Divya’s interview have been translated from Hindi.

> It's not only bad media practice, but they have to understand that it has a profound effect on patients, on their psyche, on raising false hopes, on preventing them from participating wholeheartedly into what is currently available, that is, rehabilitation because if there is a cure [patients will say] why should I go through the rehab process. (Interviewed 24.12.2012)

In Ahmed's analysis, happiness was in a state of "crisis" and functioned "primarily as a narrative of disappointment" (Ahmed 2010:7). Similarly, the notion of hope in this thesis is considered a problem that is caused and propagated by a condition of crisis. In its mobilisation by various state and non-state actors, hope yielded greater power to the "logic of choice" in medical practice rather than the "logic of care" (Mol 2010:101). The "logic of choice" perceives patients as consumers and manipulates desires, stated Mol, whereas care involves "handling daily life with a disease (Mol 2010:101). The previous chapter discussed how there was little difference in the advertising strategies used for new electronic technologies such as high definition television and stem cell therapies, both enhancing the appeal for the product being sold and/or offered. Van Lente's study analysed how HDTVs attractiveness was produced by juxtaposing its new features with older types of TVs, and also placing it in the context of other significant but irrelevant scientific innovations. Similarly, stem cell treatments were described in association with genes, the other biological entity that has also captured the imagination of the public. Patient videos and written testimonies was also a strategy used by providers that could potentially confuse patients and families about what they "want" with what they actually "need" (Mol 2010:109).

d) Hoping among "free subjects"

According to Foucault, the possession of "knowledge, competence, and qualification" is inextricably linked to power but in order for this power to be used it must involve the "actions" of both the source of power and its receiver, the subject or the patient in this case (Foucault 1982:781). The subject's own actions, Foucault emphasised, were crucial to the use of power and therefore he or she must be free to act if power is to be exercised. Since power is mobilised through actions that can be subtle—as much as it can be overtly violent—it need not be obvious in the ways it is accepted by the subject or how it is imposed. According to Foucault, the relationship that exemplified an implicit understanding of a power equation was the physician-patient relationship. The physician as the bearer of expert clinical knowledge converted patients into subjects by the mere fact of possessing knowledge that patients did not

have (Foucault 1982:781). In the context of 21st century techno-scientific developments, some of this power held by experts has shifted to lay patients and the public who have greater access to the scientific domain through new and traditional media forms and other globalised systems of movement of information and people. Although the choices of patients and families in using medical technologies like stem cells were shaped and directed by structures of state, media and the market, an individual's decisions were nevertheless perceived as outcomes of freedom to navigate information and sites of provision thereby having gained greater control of ones illness trajectory.

Power operated only through "free subjects", Foucault argued, because power is encountered by "virtue of" them being free or "being capable of action" (Foucault 1982:789-790). "Free subjects" were, thus, those individuals "faced with a field of possibilities" and freedom in other words was the "condition" or even "precondition" for "power to be exerted" (Foucault 1982:790). The clinical trial subject defined as a volunteer in scientific research also embodied this notion of the free subject. By 1980, the U.S. government had prohibited the use of prisoners and other institutionalised sections of society in medical experiments, permitting only freely consenting individuals as trial subjects (Hoffman 2000; Petryna 2009). A trial subject's decision to participate in a study was understood as an act of free will and also morally sanctioned through bioethical processes such as informed consent. As if devoid of socio-economic and other contexts, the meaning of the subject in the act of giving consent was subsumed under ideas of freedom, choice and knowledge of risk versus benefit. It was, thus, in the process of choosing, participating and knowing that the formation of the experimental subject occurred. "If I was a guinea pig it was at a great cost to me [but] that's alright, I quite enjoyed it", said Mr. Seth who had invested time and money to become a trial subject (Interviewed 28.5.2014).

e) The "good life"

The practicalities of a treatment regime in clinical settings that include daily medical routines and hospital staff encouraging patients to persevere in the face of disappointment are features of the logic of care not emphasised enough in the paradigm of choice (Mol 2010). "I have my bad moments", said Vivek, who implied that he happened to be in a "positive frame of mind" during the interview (Interviewed 26.6.2014). Another MS patient had hoped for "miraculous" results from the stem cell treatment that he called a "revolutionary technique" but in the end fell hugely short of what he had hoped for: "It was a total waste of time, money and effort. Not to forget

the great expectations of me and my wife and children", the retired army brigadier had stated (Interviewed 2.9.2014). In another instance, Dr. B had pressured Seema into doing the treatment as quickly as possible on the pretext of her daughter's age. Seema had the "most dreadful experience" of her "life", she said, looking back on the traumatic episode of her child falling seriously ill in the course of the treatment (Interviewed 26.11.2013). According to caregiver Karan, the experimental treatment "looked like a big hoax" (Interviewed 26.7.2014). Karan's father had died from motor neuron disease about a year after the treatment. In retrospect, he stated:

> We were fortunate enough that were able to gather that kind of capital to go through the procedures" but "logically it is the most incorrect thing to go for, "there are no proper guidelines, it's a very shoddy deal, you don't know what's been administered to you and what's not. (Interviewed 26.7.2014)

Deciding on a particular medical technology is "not enough" stated Mol, as the decision to use it could mean the start rather than the end of a patient's problems (Mol 2010:103). In her analysis of an advertisement of a new blood sugar monitor, Mol argued against the exaggerated portrayal of enjoyment as the result of buying the monitor. The image that depicted people enjoying a "walk in the mountains" was "enticing", stated Mol, because it showed the "promise of freedom" but it also underplayed the importance of managing erratic blood sugar levels in order to ensure that walking in the mountains was a real possibility (Mol 2010:111). In the context of "chronic disease" where health is evasive, often unpredictable and involves long-term care, the association of treatment with enjoyment becomes necessary for the morale of the patient and an important strategy used by the healthcare market. Good introduced the concept of the "medical imaginary" that made medicine a "fun and intriguing enterprise", drawing patients, doctors and the general public into a " 'biotechnical embrace' " (Good 2001:397). Wide media reporting on the latest therapies and "imminent" discoveries is a part of this "imaginary", having provoked the "affective…dimensions of biomedicine" in "professional and popular culture" and given biotechnology its distinction of an all-encompassing "enterprise" of "possibility" (Good 2001:397-398).

In Mol's opinion, medical care in its ideal form would advise patients with chronic conditions to "persist while letting go", in particularly those situations where "trying" cannot "guarantee success" (Mol 2010:106,116). The market, on other hand, never tires of promoting the " 'good life' " that can be lived on the condition that the medical

products advertised are purchased (Mol 2010:106). The idea of 'the good life' that has entered healthcare is a feature common to contemporary cultures of consumption. It is deeply ingrained in the production of middle class identity in India, and the world over, with structures of state and media responsible for producing a homogenised aspirational framework for the social group despite its wide socio-economic disparities. Included in the definition of the good life is the notion of "privileged lifestyle, privacy" and "private property", stated Choon-Piew in his analysis of gated communities where China's new urban middle class live (Choon-Piew 2009:9). The luxurious residential complexes that restrict entry to non-members have been implicated in "the politics of place-making" argued Choon-Piew, as they contribute to building a "exclusionary landscape" in China's cities that house large numbers of the "urban poor" (Choon-Piew 2009:9). Surrounded by high walls and protected by a vast security apparatus, these residences symbolise a defence—" 'real' " or imagined—of the good life from outsiders (Choon-Piew 2009:9). The assertion of middle class identity through "territorial politics" found in China is also prevalent among India's middle class and has been incorporated into healthcare institutions, as have other notions of exclusivity and limited access (Choon-Piew 2009:9). Discussed in more detail later, several hospitals in India today are modelled on hotels and shopping malls that are among the key markers of urban living and aspirational lifestyles. Hospital rooms, for instance, are categorised as "deluxe" rooms, luxury suites or regular rooms (Baru 1998:132) and every effort is made by these establishments to find a place in India's consumer culture, "turning their back on the 'disorderly' and 'insalubrious' public" health system (Choon-Piew 2009:10).

f) The stem cell: source of power and object of desire

The vast scholarship on the role of hope in contemporary medical biotechnology essentially argued that the affective realm comprising wishes, hopes and fears—some real and some not—is as much the domain of science as it is of culture. Relatively new medical technologies such as stem cells or purely cosmetic enhancements for hair growth and smoother skin are advertised as commodities full of possibility as long as the consumer is adventurous enough to experiment.

Patients of this study used terms to describe their experience with stem cells as they would perhaps for any leisure activity. Mentioned earlier, Mr. Seth expressed enjoyment in being an experimental subject (Interviewed 28.5.2014), while Vivek described his experience in China as "very nice" (Interviewed 26.6.2014). After

reading the blog of a woman with MS who was miraculously cured from stem cell treatment, Vivek had imagined his own miracle:

> I was hoping that somehow this treatment does things, that I suddenly become one of the first few people to actually get cured. I was fantasising [a little laugh] if you want to put it that way. (Interviewed 26.6.2014)

The inclusion of stem cell treatments in the repertoire of miracles, dreams, pleasure, wishes and fantasy had shaped patient subjectivities through promise and possibility, incorporating what was real and what was not, and also what could be medically possible. Hodges, for example, described cord blood banking as a medical technology that "slides neatly into the emergent fantasy-scape of this new India", offering a chance for a better life through new opportunities for risk and enterprise (Hodges 2012:1). Brown described the relationship between the two categories of hope and truth as "parasitical", in that the doubts of the present can become the rationale for believing in better and improved treatments in the future, even though the hoped for future is more fantasy than scientific fact (Brown 2005:333). The media, we saw in the last chapter, has played a pivotal role in bringing the logic of the commodity into peoples engagement with stem cell treatments—as something to be acquired and desired. The patient-consumer is at best a "chooser", but by drawing the realm of fantasy and imagination instead of treatment, research and healthcare into the treatment encounter, the individual "appears to be…creator" of his or her destiny "through illusions spread by advertising" (Robinson 2011 para 21). The language used by India's media for reporting on stem cells was similar to terms used for selling a business venture. "Home to a 1000 dreams" was how a hospital room conducting stem cell research was described by *TOI* (Kamdar 2004:3). This description was not very different from the one used by a website of a real estate consulting firm, promising "100 Dreams" to the buyers of property (100Dreams 2014). In some instances, stem cell treatments were portrayed by the industry as the first step in a person's journey to fulfilling other dreams and future life goals. An online news feature posted by the Chinese firm, Beike Biotechnology, described how stem cell treatment had empowered a patient to "pursue" her "dreams" and "career aspirations". Further in the text one learns that the young woman is still in a wheel chair but the "sky can once again be the limit" for there is a "broad range of [stem cell] treatments" "available", the piece stated at the end (Beike Biotechnology 2015).

Cultural anthropologist Williams, in his analysis of the media argued that magical qualities were ascribed to an object when the value of that particular commodity appeared doubtful (Williams 1980). The recourse to “magical inducements” was, thus, paradoxical as it indicated that society was not as “materialistic” as it was made out to be (Williams 1980:185). If it were so, Williams explained, the object would be considered important enough to sell in its original form without having to add extraordinariness to its value so that people would buy it. A “cultural pattern” was, hence, evident in which objects must be “validated, if only in fantasy” (Williams 1980:185). The writings of Williams on the power of the media in the West, in the 1960s, are relevant today as magical qualities of new products or medical technologies like stem cells are being conjured to ensure the product’s popularity among the public. As these treatments are sold for incurable conditions, the world of desire, fantasy and hope become inseparable from anxiety and doubt experienced by both seller and buyer. The parent Nita saying she “would love to do stem cells” again or Mr. Seth having “enjoyed” his experience as an experimental subject in Israel or Vivek describing his experience in China as “exciting”—all pointed to the inclusion of healthcare and medical experimentation within the consumption and production of both desire and its associated anxieties and uncertainties.

The desire for a cure, to draw from Butler, had mobilised patients and families to take action, giving them “agency” in the face of disease and disability (Butler 1997:2). Hope—used interchangeably with desire—had also, however, simultaneously formed and sustained the process of subject formation. Desire is an important element in subject formation, Butler argued, because the individual is also “attached” to the source of power—in this case the experimental treatment—making a dependent relationship with power difficult to avoid (Butler 1997:6). The experience of power is thus “paradoxical” because the treatment, for instance, was not an external imposition of force against the individual’s will but something that the patient or caregiver wanted to try (Butler 1997:1). In this relationship to the object of power that is also something desired, the subject would rather submit to it than not have access to it at all. Power in these terms is perceived as necessary for the subject, making the source of power not always easy to resist. Butler gives the example of child abuse as the manipulation of a child’s love by the object of power that is considered necessary for the child’s “existence” (Butler 1997:7). The need for survival is a “pervasively exploitable desire” stated Butler, and a power relationship of this kind is, thus, easily “exploitable” by “the one who holds out to the promise of continued existence” and therefore “plays to the desire to survive” (Butler 1997:7).

Patients similarly understood their subjection to unknown stem cell treatments as an act of survival, without which Mr. Seth explained, he would rather be dead. Choosing to be a subject was considered essential to ones existence, with the means and methods of survival themselves being defined by power structures. As the meaning of happiness and health are defined by the media, markets and medical industry, these "dominant" "interests" have left little room for the co-existence of alternative meanings and solutions to unhappiness or relief from discomfort and disability (Lock 1996:212). People, thus, unwittingly turn to these power structures to give them meaning in their lives without necessarily being aware of the power or subjection involved. According to Althusser, the unconscious imbibing of certain ideas and cultural practices that appear to be ones own actions but are in fact the workings of "ideological state apparatuses" such as the media (Althusser 2014:177), is the process of "interpellation" that "transforms" people into subjects (Althusser 2014:190). An "interpellated" subject, who in this instance is an experimental subject, is somebody who accepts his or her subject identity unquestionably or unconsciously (Althusser 2014:192). Althusser gives the example of an individual automatically turning towards a policeman on the street after being called out by him, regardless of whether the individual was guilty or not. This widely quoted example of Althusser explains the presence of power in everyday living and highlights his argument of subject formation as an effortless and instinctive exercise (Althusser 2014). Althusser's understanding of individuals as ready subjects points to Lock's argument on the role of culture being underestimated in the acceptance of new medical technologies. In her comparison of organ transplants in Japan and North America, Lock found that in 1990 the latter had performed a significantly higher number of transplants than Japan even though the two locations were at par in technological development. The easy answer for this discrepancy in the use of transplant technology was the Japanese public's distrust of the medical profession. On further investigation, however, Lock also found that these two regions defined brain death differently, with Japan considering it " 'unnatural' " (Lock 1996:229). The cultural perception on brain death was among the compelling reasons for resistance to organ transplants in Japan, not recognised as relevant enough to explain the differences in technological acceptance between the two societies. Lock argued in conclusion that it was "culture and not nature that define[d] necessity" (Lock 1996:209).

These understandings of power and its "circulation" in every day life are useful in investigating how hope, promoted by various actors, had turned middle class patient-

consumers of a medical technology into experimental subjects without breaching the bioethical principle of patient autonomy (Foucault 1982:786). The subject formation that took place while individuals went about quotidian tasks and performed activities to fulfill their needs and wishes, revealed how power—embodied in hope for stem cell cures—was normalised in the social process. As hope exerted its influence in various ways and among various actors, its value—to borrow from Ahmed—only intensified in its absence further entrenching the process of subjection. “Happiness might keep its place as a wish by its failure to be given”, said Ahmed (Ahmed 2010:1). In the pursuit of stem cell treatments, what was possible in terms of care was lost in the desire of what might be. Hope argued as a precious recourse for health management had also held its believers captive, becoming all the “more powerful through being perceived as in crisis” (Ahmed 2010:7).

As the pursuit of stem cell treatments was often mixed up with ways of seeking other objects of consumer desire, so did the clinical site become blurred with other structures in a consumer culture that are built with the sole purpose of invoking worlds of pleasure and fantasy. The following section describes how architectural design used to enhance and activate sensory pleasures in spaces like shopping malls and hotels was also applied in the building of healthcare institutions that are inclined to emphasise the experience rather than care. The better infrastructure of private sector hospitals, often found in nicer neighbourhoods and staffed by relatively less beleaguered doctors and nurses in comparison with public hospitals is easily mistaken as criteria for better care.

g) The role of hospitals in the production of middle class identity

A medical technology “ ‘laden with mythical content’ is enhanced” in its value, both medical and clinical, “ ‘with architectural imagineering’ ” of the building in which it resides, stated Mills (Mills 1993:152 cited in Kearns and Barnett 1997:173). Private hospitals in India increasingly evoke the same physical, spatial and cognitive experiences as other highly visible sites of urban consumerism today such as shopping complexes, cinema halls and restaurants. Some of the larger corporate chains like Max Healthcare in New Delhi are also located in proximity to these sites. According to Kearns and Barnett who analysed the transformed meaning of healthcare in New Zealand:

> The fact that respectable dining and entertainment establishments are juxtaposed with the clinic emphasises the degree to which health care has been normalised in…consumer culture (Kearns and Barnett 1997:176)

The hospital in China where Vivek was treated, had an entire floor dedicated to patients from abroad that he said, looked like a "five star hotel" (Interviewed 26.6.2014). For caregiver Martina, the experience of visiting a private hospital in Mumbai for her son's stem cell treatment was likened to being a "tourist" on "holiday" (Interviewed 17.7.2014). The reasons why "you don't feel it's like a hospital" said Martina, was the staff's hospitality and the pleasant environment. The doctors were "very sweet, very sweet" there was "no smell, the place is so clean, the nurses were nice, the helpers were very good, very cooperative" (Interviewed 17.7.2014). Several relatively smaller private establishments, like the one Martina visited, emulate corporate hospitals in experience, advertising, architectural style and material and are not unusual in the urban landscape of India today. Offering globally popular medical technologies and better infrastructure are also key selling points of these smaller practices. Dr. A, for instance, would tell his patients that the stem cell technologies he was offering in his hospital "is what the world is doing" (Interviewed 25.1.2013).

The corporate hospital in "imitating the five star hotels in their design" and "in the experience the patient will have" (Lefebvre 2008:99) are among "the most efficient vehicles that promote consumerism in healthcare", Lefebvre argued (Lefebvre 2008:91). Instead of blatant advertising of healthcare that is "difficult to market" these establishments attract customers by selling their "medical excellence" efficiency in "management and "corporate governance" (Lefebvre 2008:95). Every effort is made, in other words, to establish a reputation of difference from derelict structures that house tertiary care government services that until the 1980s-1990s, Indians had little option but to use unless they went abroad for treatment (Baru 1998; Lefebvre 2008). In the case of Apollo, India's first corporate healthcare chain, Hodges examined how the enterprise strategically used the media to portray an image of a hospital as a "patriotic project" offering " 'ordinary Indians' " a "new model of healthcare delivery" that previously only wealthy Indians could access in foreign countries (Hodges 2013:243). Hodges, while arguing that the question of who is the "ordinary Indian" is too "vexed" an issue and must be excluded from the analysis "for the sake of simplicity", refuted each public statement of Apollo with corresponding facts (Hodges 2013:243). For instance, Hodges argued that Apollo did not herald the change that it

claimed to have brought to Tamil Nadu's health system. Chennai, its capital city, already had "high-quality medical care" for its relatively "large middle class population" that could afford specialty services prior to the establishment of Apollo's first hospital (Hodges 2013:244-45). Nevertheless, the successfully maneuvered public image of hospitals like Apollo as harbingers of change and modernity were very much a part of the "wider processes of urban structuring" that took place during the liberalisation of India's economy (Fernandes 2006:142).

Fernandes writes about the emergence of a "new urban aesthetics" since the 1990s that has led to the development of spaces where the middle class can "assert" and claim an identity different from other groups (Fernandes 2006:139). "Beautification projects" are an example of how successful negotiations between middle class member-based organisations and state civic authorities are transforming public spaces into exclusive areas such as a private "jogging strip" (Fernandes 2006:147). The difference in the dynamics of urban space today, Fernandes argued, is the growing segregation between areas inhabited by lower income groups and middle-class neighbourhoods. As public spaces and every day leisure activities like running in a park get privatised, the idea of the public space is increasingly being transformed into signs of privilege available only to the "consumer-citizen" (Fernandes 2006:187). Geographical configurations have thus not only been physical enablers of middle class practices but have also infused the urban landscape at large with "meaning" that functions to embed middle class identity (Kearns and Barnett 1997). The hospital, included in this "spatial reconfiguration" post the 1990s, represented an "idealized vision" of India embracing "globalization, modernisation and technological progress" (Fernandes 2006:146). With spaces themselves associated with positive change, the private hospital was assumed, to draw from Ahmed, as a "good" place even prior to its use (Ahmed 2010:6). This is not to say that patients and/or caregivers did not have negative experiences with private facilities but rather to stress that the logic of consumer choice in healthcare has confused the right choice with the new, different comfortable and modern, in other words, everything that the public health system is not. The space itself has, thus, come to signify—along with the new technology—a break from the past, a departure from the "old" and in its newness gives room for hope and change (Baviskar and Ray 2011:11). The middle class origins of Reddy, Apollo Hospitals' founder, had appealed to India's growing affluent sections who wanted the latest health technologies close to home (Lefebvre 2008). The IVF clinic in the country today is a symbol of the largely "urban-based Indian consuming class's willingness to seize a moment of possibility", said Vora (Vora 2013:97). Through

"architecture" and "advertising" that Kearns and Barnett described as the "dominant texts in contemporary social life", the public are attracted towards different and new ways of consumerism (Kearns and Barnett 1997:173). The new does not necessarily mean good but just a "shinier imitation of the government and charitable institutions" that were built on "long-standing" principles of a health care model of integrated care (Hodges 2013:248). The multitude of private health institutions in India's towns and cities are no comparison in capacity or function to corporate run medical establishments, yet they seek to emulate the message of the corporate hospital—of building a "business culture as a hallmark of quality" and a means "to build trust among middle class patients" (Lefebvre 2008:95).

Conclusion

In various "symbolic, material, and attitudinal" practices, a middle class identity has been perpetuated among those who fall within its complex socio-economic structure (Fernandes 2006:141). The state, "either through a passive form of complicity or through more active forms of intervention", played a crucial role in the politics of exclusion that has produced this middle class identity (Fernandes 2006:154). In the context of stem cell experimentation and its normalisation, the politics of exclusion that has been so central to developing an understanding of the new middle class (particularly the dominant class) has been disrupted by a new politics of access that is emerging as these unproven treatments are embedded in the healthcare system and in daily lives, as a common therapeutic alternative. A non-traditional subject population is being drawn into "experimental orders" adding an entirely new dimension to what it means to be middle class (Petryna 2005:184). Patients (and caregivers) from middle class backgrounds were not the usual targets of human medical experimentation. They arrived at the experimental site of their own volition and by mobilising various personal resources. In the context of incurable conditions, the notion of consumer-choice by which many families operated was a flimsy one but also easily exercised in India's commercialised health system, and promoted by a media prone to sensationalising news. The term consumption, often used interchangeably with consumerism, includes access to knowledge and information, the media, use of social networks and other resources that need not necessarily be purchased through the market (Sturgeon 2014). With the ability to access these various kinds of capital, a hallmark of being middle class, the patients and/or caregivers experienced experimental stem cell treatments as a middle class activity—of having been given the opportunity to try something new and that which had generated global interest. To borrow from Cohen's analyses of India's

sterilisation policy, the patients of this study became experimental subjects "*as if*" of their own making and "*as if*" in doing so they also became "modern" (Cohen 2004:166-167). Cohen argued that a certain kind of "citizen-body" was shaped by India's population control programme, an integral component of the state's key prescriptions for achieving modernity and development. The poor, the main targets of the population policy, were assumed to be only "subjects of passion" without "reason" but were later transformed by the sterilisation operation into subjects "capable of…reason" (Cohen 2004:166). In the context of organ transplantation, Cohen described the development of another type of "citizen-body" that aligns itself with the developmental and "modernization" agendas of the state after the transplant surgery has occurred (Cohen 2004:166-167). Although Cohen defined both organ donors and recipients as subjects of science, he divided them into the categories of "bioavailable" and "operable", a distinction that reflected social hierarchies in the process of subject formation (Cohen 2004:167). For those who received organs, an entitlement to "modern citizenship" had been enabled, stated Cohen, unlike the economically disadvantaged donors who were only turned into a biological resource (Cohen 2004:167). This logic of survival or freedom of choice that operates in how medical technologies are used was reversed and mixed up in the context of stem cell experimentation. There was no clear positioning of bodies between those from privilege and access, and those whose bodies must be controlled or used. More than half the patients of this study were both "bioavailable" and "operable" subjects (Cohen 2004:167). They were the source of stem cells and the recipient of the medical technology, making them experimental subjects and modern citizens simultaneously.

Chapter five

Stem cell experimentation as consumer practice: implications for the future

The normalisation of stem cell experimentation in urban middle class life can be understood as a crisis, "*in extremis*", of both medicine and culture (Petryna 2005:4). The majority of this study's patients or caregivers had paid for unproven stem cell treatments in the private sector and more than half were treated with stem cells extracted from their body's bone marrow. The provision of these treatments, we saw in previous chapters, was embedded in ways that made boundaries between ethical and unethical, regulated and unregulated, private and public, often difficult to demarcate. In addition to existing relationships within the health sector, providers were also linked with the biotech industry such as stem cell processing firms and cord blood banks, with stem cell treatments ensconced in routine commercial and healthcare activity. The patients (or caregivers) who received treatments in clinical trials did not choose one form of provision over the other but took whatever kind of stem cell treatment that was on offer. The patient-doctor encounter was one among the many sources of information on these experimental treatments. Individuals and families learnt about the treatment in various ways such as informal networks, a patient organisation, special educators and the media. There were also those individuals contacted by stem cell agents who operated as middlemen between patients and providers. A private sector charging patients for offering their own bodies, as both a site of experimentation and a source of potential cures, represented what Kent and others called a "high form of consumerism" (Kent *et al* 2006:17). Clinical settings in offering stem cell treatments for incurable conditions had performed a role similar to leisure sites—where wishes were made or temporarily enabled. These treatments sold as "promissory" technologies were no different from interventions for human enhancement or reproductive assistance (Sexton 2011:1). Although IVF and plastic surgery, for example, have clinical uses, these medical technologies shared with stem cells the common goal of mobilising the body as a "utopian site" (Stern 2006:71). The "fitness and beauty industries" exemplified the market's "preoccupation with the body" as a means to satisfy "desires and fantasies associated with a consumer culture" (Stern 2006:71). Understandings of bodily perfection, produced by an industry in pharmaceuticals, biomedical techniques and procedures have become globalised cultural standards and in recent

years, stem cells have also been included in the growing repertoire of human enhancement technologies. Advertisements selling stem cells for hair growth and perfect skin, for instance, are not unusual in India's metropolitan cities.

A consumer culture in its truest form in India was first experienced in the 1990s when commodities such as "cells phones, washing machines, and colour televisions" became easily available (Fernandes 2006:30-31). The advertising of consumer goods that embodied new lifestyle patterns played a significant role in "enframing" the identity of India's new middle class (Fernandes 2006:30-31). This social group, in all its diversity, was encouraged to purchase goods if they desired the new and different, the contemporary and modern. Included among these goods were also new medical technologies that were introduced into India's health system with assumptions of improved and better healthcare. Stem cell treatments for providers, family members, patients and scientists, similarly symbolised a claim on the future and participating in what was current and global. Any obstacles in engaging with the science or the treatment were perceived by some respondents as a denial of opportunity to alter their private or professional lives.

The biotechnology industry today is no different from a consumer market in how it uses advertising strategies to influence public opinion on a new medical technology. Discussed in previous chapters, Brown's analysis of private CB banks showed how the language of hope as opposed to fact is now foundational to the biosciences. The appeal to the affective was also evident in stem cell operations of this study. The major actors had all participated in the "political economy of hope" of stem cell treatments including the clinical trial industry (Novas 2006:289). For instance, a public hospital's pilot study had provided autologous, bone marrow stem cell treatment to a child with muscular dystrophy despite scientific claims on the limited potential of bone marrow stem cells for non-haematopoietic conditions. Additionally, misleading information on the hospital's consent form regarding the therapeutic potential of autologous bone marrow bore further testimony to the analysis of Brown and others on the increasing irrelevance of scientific data and the impunity given to hope in the current discourse on biotechnology (Brown 2005:335). The same consent form had also simultaneously stated the fact that there were no guarantees in treating a progressive condition like muscular dystrophy. In this blurring of truth and hope, "who has the authority" to decide what to hope for and how do we "judge" if the "expertise" can be relied upon, are some questions that have gained prominence as actors in their engagement with medical technologies are left to

ultimately develop their own meanings of truth and uses of hope (Brown 2005:336). The many "unreliable unknowns" of stem cell science were, therefore, open to interpretation and gained greater validity and traction in markets, policy circles, in institutional activities, and in the decisions individuals made about knowledge seeking and risk-taking (Brown 2005:336).

Stem cell experimentation among the middle class was enabled by and constitutive of consumer choice in healthcare and a culture of consumption. The future implications of stem cell experimentation becoming a consumer activity that is integrated into the practice of daily living, current hopes and future plans of patients, caregivers and providers is the key issue raised in this chapter. In contexts of constant change in expectations in medical biotechnologies, the discussion here is perhaps as unstable as the future of stem cell science and its consequences for new experimental populations. An attempt, nevertheless, is made to provide an analytical framework for the emergence of stem cell experimentation as a signifier of the middle class. The treatment's rootedness in middle class life and healthcare networks throws open many questions about emerging relationships between society and medical technologies than there are possibly answers for. Together with STS scholarship that reminds us of the significant role of social processes in medical innovation, the discussion in this chapter also brings forth recent understandings of biopolitics that project different futures, some more pessimistic than others.

The middle class population as a target for stem cell experimentation could suggest that nobody, not even the relatively well off and resourceful, is safe from questionable technological intervention or free of biomedical control. On the other hand, stem cell treatments being offered as an easy and inevitable alternative for those willing to experiment could signify the entry of unproven medical technologies into the discourse on individual rights and freedom of choice. The rights framework has increasingly dominated current debates on the surrogacy industry in India, where arguments made by its proponents on the right to choose have undermined the demands for reproductive justice for women who become surrogates. In either of the two scenarios—of choice or control, a dystopian present can be argued and a hopeless future can be imagined. In this future, bodies of all kinds would be exposed to unproven technologies, seemingly by choice, in contexts devoid of structures of trust and shifting sources of truth (Brown 2005). According to Agamben, Italian philosopher and theorist on biopolitics, " 'in our age all citizens can be said, in a specific but extremely real sense, to appear virtually as *homines sacri* ' " (Agamben

1998: 111 cited in Lemke 2011:58). The term "homines sacri" was used by Agamben to refer to those individuals whom the state “could kill with impunity” (Lemke 2011:54). Central to his well-known argument was a particular kind of subject, the “*homo sacer*” whom Agamben derived from ancient Roman legal history. The “*homo sacer*” was a person deprived of legal status or citizenship rights and therefore lived a life that Agamben described as “bare life” or “zoé” (Lemke 2011:54). This “bare life” he contrasted with “*bios*” or a life that was fully engaged in polity and enjoyed state protection (Lemke 2011:54). The different kinds of life formed at the hands of the state were conceptualised by Agamben on the basis of Nazi Germany’s concentration camps. It was in these camps, he argued, that “ ‘bare life’ ” was produced. For Agamben, the state was a “sovereign power” that by “the rule of the exception”—had reduced the life of *homo sacer* to “his” mere “physical existence” (Lemke 2011:54-55). In Agamben’s analysis of contemporary times, the “ ‘*state of exception begins to become the rule*’ ” and the production of “ ‘bare life’ ” was no longer confined to a particular site or social group (Agamben 1998:168-169 cited in Lemke 2011:56). “Asylum seekers, refugees…the “brain dead” and even individuals killed in road accidents were later included in the category of “ ‘bare life’ ” (Lemke 2011:55). As “ ‘bare life’ ” is normalised and begins to reside in “ ‘the biological body of every living being’ ”, the concentration camp becomes an abstract concept (Agamben 1998:140 cited in Lemke 2011:58). Agamben’s argument of “bare life” as all pervasive is described here as it can be quite literately transposed onto the argument of normalisation of stem cell experimentation in everyday life (Lemke 2011:54). If “bare life” is considered the essence of polity today, as Agamben argued, then the middle class as experimental subjects or potential recruits for unproven treatments could easily be situated in Agamben’s understanding of biopolitics (Lemke 2011:54). These were adults and children who were excluded from the business of daily living and prevented from functioning to their full capacity due to social stigma and other barriers to physical mobility, cognitive functioning and societal acceptance. Physically and cognitively impaired, they were rendered “ ‘useless’ ” by the state and civil society, making participation in mainstream life a daily challenge (Lemke 2011:61). Experimenting with unproven treatments was perceived as their only recourse for change and for some their only hope for survival.

As experiments moved from laboratories and clinical spaces “into the larger field of material culture”, “different populations” were produced as “experimental bodies”, argued Towghi and Vora. In this process of subject formation, according to the authors, there was no “explicit marking” of “objects of experimentation or the space

of the experiment as a laboratory" (Towghi and Vora 2014:2-3). Jasonoff similarly argued that biomedical experiments were no longer contained within an "ivory-tower science" as the nature of science itself has changed and the study of biological entities defy traditional paradigmatic structures of conducting scientific experiments (Jasonoff 2006a:2). Scientific research "can move through generations" and knowledge production does not necessarily conform to old understandings of time and space (Jasonoff 2006a:5). A stem cell line, for example, that originates in a laboratory in a particular corner of the world can be transported anywhere. Jasonoff, in arguing the impossibility of "containment" of the medical experiment today, thus emphasised not only the redundancy of physical confinement to a particular experimental site but also the difficulty of conceptual, political, ethical and as well "temporal containment" (Jasonoff 2006a:5). For instance, clinical trials that are sponsored by pharmaceutical companies in the U.S. and Europe are also conducted in low-cost sites in Asia and Africa. This worldwide expansion of clinical research led to an "unprecedented" increase in "experimental activities" that were not always easy to map or "account for" (Petryna 2007:291-291). The increase in global clinical trials using local populations was also witnessed in India when it liberalised its drug development sector. Discussed in the previous chapter, the development of India's clinical trial industry resulted in the emergence of a whole host of actors who performed different roles in clinical trial operations. As the private sector set up its clinical research enterprises, the state issued regulations and legislated oversight bodies in compliance with globally accepted ethical and scientific standards to ensure smooth operations of the industry and scientific research.

As biomedical experiments increasingly challenged familiar boundaries of all kinds, and scientific potential seemed limitless in its capacity for biological manipulation, governments the world over attempted to "produce moral containment" through various "formal mechanisms" (Jasonoff 2006a:7,9). These instruments of control such as the law and bioethics, discussed in chapter one, operated on the interests of not only the state but also other actors, serving the needs of some more than others. In the context of contemporary medical biotechnologies such as stem cells, the relationship of the state to its subject was, therefore, more complicated than what Agamben analysed (Lemke 2011). The ordinary middle class individual being drawn into the fold of stem cell experimentation in India was not an outcome of organised state machinery and neither was it, to draw from Lemke, an obvious result of state prescribed action (Lemke 2011). The previous chapters made evident that a range of state and non-state actors were involved in the micro and macro processes of

normalisation, directly, indirectly or inadvertently. Some of these actors and activities were already established prior to stem cell practices and some new ones had emerged. Apart from patients, families, individual clinicians and institutions, the others included cell processing firms, CB banks, hospital networks, ethics committees and ethical procedures. If patients and caregivers, who seek treatments in this context of several actors, are to be included in the category of "*homines sacri*", it becomes imperative to explore the differential relationships between the state and the public and to delineate the "mechanism of differentiation that distinguishes between different values of life" (Lemke 2011:58). Agamben failed to do this exercise, stated Lemke who argued:

> The principle danger today is not that the body or its organs will succumb to state control…On the contrary, the danger is that the state will…hand over decisions pertaining to the value of life…to the realm of science and commercial interests, as well as to the deliberation of ethics committees, expert commissions, and citizen panels (Lemke 2011:61).

Therefore biopolitics, Lemke argued further, also needs to look at how individuals with legal rights are governed and the differences between them that invariably dictate the nature of their engagement with the state. The middle class patients and families of this study had undergone an arduous and protracted process of diagnosis of the condition they sought cures for. The health system failing to provide sound medical advice for many and the overall lack of appropriate avenues for care, were obvious outcomes of consistent policy neglect in India for persons with disability. Financial strain, the lack of inclusionary mechanisms in mainstream educational institutions, social exclusion and loss of a working life, were among the many challenges faced by caregivers and patients. In other words, it is important to emphasise here that a middle class status did not preclude hardship or the manipulation of hope by providers and the media. At the same time, however, this heterogeneous group was also perceived as the beneficiary of India's liberalisation and globalisation policies. The respondents operated as autonomous individuals in every day life with various options for enacting their hope through informal and formal networks, treatment alternatives, travel in India and abroad, and access to various knowledge sources including the Internet. In these actions "innovation may offer not only a mitigation" of the "debilitating effects of illness and disease", stated Brown, "but also the redefinition of their meaning within the life course" (Brown and Webster 2004:162). Despite the feelings of ambivalence and disappointment expressed by

some patients and/or caregivers, the discussion in chapter two indicated how the overall experience of stem cell treatment had also given these individuals the tools necessary to regain control of their life circumstances. The narratives of those who felt disillusioned with the health system had ended with a greater awareness of irresponsible providers and a renewed resolve to tackle societal resistance to disability. For private providers, on the other hand, offering stem cell treatments was perceived by some as acts of entrepreneurship and defiance of the state that had neglected the needs of clinicians seeking legitimate research opportunities.

The engagement with stem cell treatments for all these individuals—provider, patient or caregiver—were thus embodied acts of "becoming", wanting and planning in the present and for the future (Brown and Webster 2004:166). Consumerism, argued here as the "chief basis of the social order" had also commodified the experiment, merging it with other acts of fulfilling needs and other forms of paid-for healthcare (Poster 2001:2). The process of normalisation that occurred through various hospitals, individuals, networks, industry and daily acts were familiar and also involved the emergence of new types of relationships — with the body, patient organisations, healthcare, and the market that comprised biotech companies and individual operators (Kent *et al* 2006). Those who underwent autologous bone marrow treatments, for example, contributed to producing the stem cell concoction and simultaneously were also its consumers. Patients (and caregivers) saw no harm in autologous treatments, for their own bodies and not a foreign entity were the source of stem cells. The experimental treatment was offered with other routine therapies such as physiotherapy and occupational therapy, merging an unproven intervention with other forms of care. To recall Franklin, in this paradoxical engagement with an experimental technology that was normalised, yet new and different, the "taken-for-granted boundaries" between care and experiment, production and consumption, commodity and healthcare had "become open to question" (Brown and Webster 2004:105).

In the context of these new corporeal and social formations, Cooper, Waldby and others brought attention to the definition of the medical experiment and whether its meaning must change to keep pace with society's changing engagement with new medical technologies. These authors argued how markets have been instrumental in establishing a "mutable" relationship between experimentation, enterprise and care (Waldby 2012:179). To this argument Cooper also introduced the relatively recent dimension of participation in medical experiments as an individual's "right to assume

risks" (Cooper 2012:28). The notion of medical experimentation as an act of self-expression and patient assertion has its origins, Cooper reminds us, in AIDS activism of the 1980s. People with HIV/AIDS in the U.S. had demanded the right to use "highly experimental, potentially high-risk new antiretroviral drugs" well before the safety and efficacy of these products had been proven (Cooper 2012:22). The activists had protested the stringent regulations in the U.S. for clinical trials and demanded the right to use experimental drugs (Cooper 2012:28). For these individuals living under the shadow of imminent death, waiting for the protracted process of a clinical trial was futile. Under such dire circumstances, the medical profession had also participated in HIV/AIDS activism by illegally importing unproven drugs and conducting "underground trials" (Cooper 2012:29). The movement eventually had its successes, with the U.S. Food and Drug Administration (FDA) introducing changes that allowed "terminally ill" patients access to "investigational new drugs" with certain stipulations built into the rules (Cooper 2012:29). These developments of patients defying regulations to protect their interests were ironic, argued Cooper, in the light of the Thalidomide scandal in the 1960s, that provoked drastic reform in clinical research in the U.S. and also significantly impacted global rules. Today, Cooper discovers patient groups in the U.S. that were using the law to demand a "formal recognition of the right to self-experiment" with "unapproved drugs" (Cooper 2012:31). Their activism was different from the AIDS context when the movement flourished in relatively grey areas of law, ethics and medicine. According to Cooper, the recent demand for the right to self-determination with regard to experimental treatments was also being mediated by the pharmaceutical industry. Cooper described a "novel method of commercial drug production" adopted by drug companies to derive clinical data from social networking sites such as "PatientsLikeMe" (Cooper 2012:32). Set up in 2006, this site provided a platform for patients to share their experiences of using drugs, the "dosage", "side effects" and options for treatment. It also enabled its users to connect with other patients at the same stages of the particular condition (Cooper 2012:32). Patients registered on this site represented a wide range of conditions that included Parkinson's, AIDS and multiple sclerosis. The site's software had the ability to collate patient data in formats compatible with clinical trials, making it highly valuable to the industry that could easily access drug consumption practices without having to invest in costly and time consuming clinical trials. In this unconventional experiment, the pharmaceutical industry had first targeted its consumers and then involved them in co-producing "scientific knowledge", having also "mobilized new patient communities" as subjects "(perhaps unknowingly)" (Cooper 2012:37). According to Cooper, in this "user-

generated" form of "innovation the authority over scientific knowledge is no longer held by scientists alone but "increasingly outsourced to…producer-consumers" (Cooper 2012:37).

As novel as this experiment might seem, it was also an indication of desperate measures being undertaken by the pharmaceutical industry currently facing an innovation crisis (Cooper 2012:18). Attempts to revive innovation have been made by governments globally through their support of translational research that requires greater collaborations between the clinic and laboratory. India also supports translational research in stem cells and other areas. As translational medicine becomes an integral component of biotechnology policy, the assumed direction of translation from the laboratory to the clinic has been criticised as too simplistic and unrealistic a paradigm. Cooper cited critics who argued that policies for translation needed to incorporate "a return traffic of information from the clinic to the basic biomedical research of the laboratory" (Cooper 2012:26). Also mentioned in chapter three, research on the currently established hematopoietic stem cell treatments demonstrated a constant back and forth from clinicians to basic scientists, over a period of time, before it was introduced into regulated practice. Critics of current translational medicine subscribed to precisely the kind of research atmosphere of the HSC cell that enabled a more dynamic relationship between the bench and bedside. "Unexpected events" that could potentially drive innovation were more likely to arise in the clinic, critics claimed, than in a clinical trial that is designed to control uncertainty (Cooper 2012:26). Drug development regulations in India and the world over consider data on new interventions emerging from the clinic outside the purview of scientifically valid research protocols. Stem cells are categorised as " 'drugs' " in the 2017 version of India's national guidelines for stem cell research (ICMR and DBT, GOI:2017:13) on the basis of the definition of "investigational new drug" (IND) given in India's Drugs and Cosmetics Rules of 1945[1] (Department of Health, GOI 2010). The inclusion of stem cells as drugs in the guidelines indicates that the same rules apply for stem cell research as for the drug approval process. Any use of stem cells outside the framework of government approved clinical trials is defined as "unethical" and malpractice" (ICMR and DBT, GOI:2017:4).

[1] According to the Rules an IND is a "new chemical entity or a product having therapeutic indication but which have never been earlier tested on a human being" (Department of Health, GOI 2010:144)

The ineffectiveness of regulations in controlling routine practices in unproven stem cell treatments is clearly argued in this thesis with supporting literature on other medical technologies. We saw in chapter three that guidelines and rules were in some instances manipulated to work in the provider's favour. The implementation of rules would be complex at best, as stem cell activities were also embedded within regulated spaces and clinical trials that have given little assurance of ethical conduct. The credibility of clinical trial operations, that is the only form of state recognised protection for research subjects, has been compromised in various ways: unethical methods of subject recruitment, the redundancy of informed consent in contexts of desperation and poverty, the questionable assessments of risk versus benefit, the lack of transparency in negative outcomes of data, the overburdened and unprepared ethics committee, the overriding interests of trial sponsors and institutions, opportunistic clinicians and failures of compensation for trial subjects in cases of side-affects or death—are issues that have been well documented by academics, activists and the media.

The results of regulations have been "paradoxical" according to critics of mainstream translational research. This is because:

> Clinical innovation proceeds in a completely unregulated manner, without feeding into formal research protocols. And yet, historically the vast majority of new drugs have been discovered through innovation in the clinic (Cooper 2012:26).

Whether unregulated stem cell provision in India is a potential source of innovation is a subject that lies beyond the scope of this thesis. The question being raised here, however, is if the state can bypass, without consequences, new subject populations in the light of the changing "politics of the experiment", debates on the untameable nature of medical experimentation and the resulting reconfigurations of risk, the individual and the body (Cooper 2012:23). India's membership with the WTO and its own national policies in biotechnology and drug research, makes the country highly susceptible to global developments. The U.S. FDA, as Cooper pointed out, wields considerable influence on drug development practices globally, including in India and moreover, the country continues to dominate the clinical trial market today. If its drug companies are challenging traditional research paradigms and seeking new kinds of consumer-subjects, albeit in small steps, India will not be immune to these developments. The scientists and clinicians of this study had also expressed the urgent need for bringing the agendas of the clinician and researcher closer together

in the larger interests of science. There are, thus, meso factors and micro level activities involving the aspirations and interests of various actors that cannot be ignored from policy frameworks. This thesis describes the ease with which information on stem cells was disseminated through the popular media, Internet, friends, relatives, doctors and hospitals. Hope for various reasons: cures, medical care, research and or profit, was manifest in the interests and activities of the respondents and in the analysis of media reports. As problematic as the role of hope was in the negotiation of new and experimental medical technologies like stem cells, "it is simply not feasible to place ourselves objectively outside the dynamics" of expectations, argued Brown and Webster (Brown and Webster 2004:180). Stem cell biology, tissue engineering, genetics etc. are all areas situated within narratives of revolution, change and forward movements into techno-scientific futures. These fields encompass the broader visions of "customized medicine" that Thompson argued, could change our future "in ways we cannot predict" (Thompson 2013:7). Hope, therefore, functioned as an "organizing" force for the industry, and while it brought "uncertainties" it also provoked, sustained and energised the various interests involved (Brown and Webster 2004:179). Regulations helped steer hope in a particular direction and served to "discipline" society's engagement with medical technologies rather than prevent or change it. In other words, technologies do not " 'speak for themselves' ", argued Brown and Webster, but rather were enabled by existing " 'socio-technical regimes' " which have consequences for individuals and their relationship to illness (Brown and Webster 2004:42).

The state in its support of new biomedical technologies and the consequent harmonisation of regulations with global standards had also reaffirmed "the power of the biomedical model" in the research, diagnosis and treatment of disorders (Brown and Webster 2004:168). The public hospital's pilot study on bone marrow stem cells for muscular dystrophy, mentioned earlier, clearly demonstrated the medical profession overextending the limits of medicine. In offering a treatment widely known for its inefficacy in non blood-related disorders, the institution had perpetuated biomedical definitions of a normal and abnormal body, determined only by its ability to receive or resist medical interventions. The biomedical model assumes that "there is a cured 'normal' that everyone could or should be", stated Thompson (Thompson 2013:49). She argued that the excessive emphasis on cures by those in support of hESC research in the U.S. had done a disservice to disability rights. Although many prominent individuals living with disability in the U.S. have supported efforts to hasten research for clinical use, the focus on translational medicine, Thompson stated, had

only emboldened medicine's role in disability at the cost of other significant social and environmental factors that need different interventions. Scientist A of this study similarly argued that medicine would have to recognise its limitations and consider the "quality of life" of the patient (Interviewed 6.12.2013). Since hESC research is fully integrated within scientific activity in the U.S. despite the controversies, Thompson called for a "good science" that redirects its concerns from a "pro-curial frame" and the ethics of embryos to "disability justice" (Thompson 2013:27). In India too, the perception in policy and practice of hESC research as the key area demanding ethical and regulatory attention seems increasingly disproportionate to developments in stem cell treatments that are catering to atypical experimental subjects. The emphasis on the clinical trial and ethical bodies as the only platform of engagement between the state and other actors is a model that at present is ridden with its own inherent difficulties that might prove redundant in the future or rather function in its existing capacity of providing only superfluous measures to safeguard the interests of patients or human subjects. There were already deeply embedded market and provider interests within regulated frameworks involved with stem cell provision. The links between providers and industry, although a known phenomenon in the health care system, were in some instances indiscernible in the highly individualised relationships formed in relation to stem cell activities involving autologous bone marrow and cord blood sources. The sources for procuring cord blood stem cells and storage, for instance, were legitimate firms, well known in the biotechnology business but also obviously involved in covert networks of unregulated stem cell treatments. Autologous adult stem cells that researchers claimed were relatively safer and simpler to use clinically than the hESC, thus, raised other concerns related to treatment and procurement. The extent and nature of the use of placenta/foetal cells, also included in the adult stem cell category, was not clear although placenta cells were used in one case.

This distribution of risk, ethics and hope in stem cell science brings us back to the biopolitics of Agamben who argued that human lives are valued differently — divided between those selected to live fulfilling lives, and those who are deemed worthless (Thompson 2013). Implicit and explicit in the rules and guidelines that govern medical technologies such as stem cells, is an accommodation of interests that decide research priorities, the specific kinds of subject populations needing different types of protection to further particular agendas, and which stem cell has greater or lesser moral value. If stem cell research does deliver on its promise, the treatment in broad terms is likely to be accessible to only those with financial capital. These

treatments would require high-end infrastructure that only “super speciality hospitals” could afford, said Scientist A (Interviewed 6.12.2013). The scenario could later change, said the Scientist, but only if there are major breakthroughs in understanding certain fundamentals in stem cell biology. Currently, there are also difficulties in expanding adult stem cells in-vitro, which could hamper their potential in developing treatments for wider public use. The likely provision of stem cells would therefore be very specialised. Middle class populations are usually the key markets for expensive treatments whereas those with access to basic healthcare are made experimental subjects. The “vulnerable” according to India’s recent national guidelines for stem cell research, “simply implies…the economically disadvantaged” whose “capability to protect oneself from…risks” is undermined due to “decreased freewill…to make informed choices” (ICMR and DBT, GOI 2017:52). The middle class subject of this study cannot be included in this definition by any standard. The respondents were individuals who had the means to search, question, access resources and take action if they so desired. Their activities around stem cells were enacted in settings and framed within ideas that were already considered acceptable and normal: the commercialisation of health, the primacy of medical solutions for physical and cognitive disability, and the pervasive domain of the media as a source of information but also inducement and influence. This made experimentation seem the normal thing to do and the risk of trying something new worth taking. The enactment of hope was a defining feature of middle class subjects that set them apart from the poor and vulnerable. It is through “everyday practices” of exclusion, stated Fernandes and Heller, that the middle class “reproduces its privileged position” (Fernandes and Heller 2006:495). The seeking of stem cell treatments was another such “exclusionary” practice (Fernandes and Heller 2006:499). Except in this case, keeping the poor away from the ambit of hoping had functioned as a means of their protection from a currently failed promise and the burden of failure that was perceived as personal.

A “social disordering” in the words of Brown and Webster is, thus, taking place, where the middle class is most likely to be the consumer of stem cell technologies and also its experimental subject (Brown and Webster 2004:172). As unproven treatments become included in the discourse on consumer choice, everybody could be a potential subject, rich or poor, with the common caveat of nobody accruing any benefits now or in the future. What makes stem cell research different from other kinds of scientific investigations is that its future is left open to promise and possibility due to the high degree of uncertainty emerging from scientific sources, and not

despite it. There is the relatively recent discovery of iPS cells in which great hope has been invested. Stem cells may never yield therapies in large numbers or for mass public consumption, but the discovery of the iPS cell could significantly alter our understanding of the human body, said Thomson, a pioneer of stem cell science (Baker 2008). In this endeavour for what could be, stem cell treatments in this study were another symptom of a life in which the enactment of hope was an increasingly complex phenomenon. The new practices and opportunities of hoping that stem cells provided were facilitated and shaped by several forces — the market, the media, national policies and global developments, without which hope would not have been present in the everyday life of patients and caregivers. Hope "does not just come about automatically" implied Zimmermann; rather "it's a product of experience, failure, and resistance to an everyday acceptance of reality" (Thompson 2013:7). For patients and families, stem cell treatments had functioned as a means by which they could "transcend" the reality of daily life (Thompson 2013:8). A life made so harsh, that even in the experience of healthcare, there was no escape from the logic of a luxury consumer good, in whose consumption was "an illusory sense of freedom and self-determination" (Poster 2001:2).

Appendix A: Key stem cell research/therapy institutes

Type of Stem Cells	Public/Private* Institutes
Embryonic Stem Cells	National Institute for Research in Reproductive Health, Mumbai
	National Centre for Biological Sciences (NCBS), Bangalore
	National Centre for Cell Science (NCCS), Pune
	National Brain Research Centre (NBRC), Manesar
	Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Bangalore
	Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvanthapuram
	*Reliance Lifesciences, Mumbai
Hematopoietic & Bone Marrow Mononuclear Cells	Christian Medical College (CMC), Vellore
	Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPIMS), Lucknow
	Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh
	Manipal Hospital, Bangalore
	All India Institute of Medical Sciences (AIIMS), New Delhi
	National Institute of Immunology (NII), New Delhi
	Indian Institute of Science (IISc), Bangalore
	Research &Referral Hospital, New Delhi
	Indian Institute of Technology (IIT), Chennai
Limbal Stem Cells	*LV Prasad Eye Institute (LVPEI), Hyderabad
	R.P. Centre, AIIMS, New Delhi
	Regional Institute of Ophthalmology, Kolkata
Neural Stem Cells	NBRC, Manesar
	National Institute of Mental Health & Neurosciences, Bangalore
	NCCS, Pune
Mesenchymal Stem Cells	CMC, Vellore
	SGPIMS, Lucknow
	Manipal Hospital, Bangalore
	*Stempeutics, Bangalore (focused on therapy)
	*Reliance Lifesciences, Mumbai
Liver Stem Cells	Centre for Liver Research & Diagnostics, Hyderabad
	Centre for DNA Fingerprinting & Diagnostics, Hyderabad
Pancreatic Progenitor Cells	National Institute of Nutrition, Hyderabad
	NCCS, Pune
Cardiac Stem Cells	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvanthapuram
Muscle Stem Cells	Centre for Cellular & Molecular Biology, Hyderabad
Cancer Stem Cells	IISc, Bangalore
Stem Cell Banking	*Reliance Lifesciences, Mumbai
	*LifeCell International, Chennai
	*Nichi-In Centre for Regenerative Medicine, Bangalore
	*Cryosave, Bangalore

Source: ABLE Report for DBT, GOI (2012:35)

Appendix B: Informed consent forms

Informed Consent Form (Patients)

Part I:
Information Sheet

1. Information about the researcher
My name is Rohini Kandhari. I am a public health (PhD) student at the Jawaharlal Nehru University (JNU) in New Delhi. My address is:
C/O Centre of Social Medicine & Community Health, School of Social Sciences
Jawaharlal Nehru University, New Mehrauli Road, New Delhi – 110067.

2. Purpose of my study
The purpose of my study, entitled 'Stem Cell Research and Experimentation in India: Mapping Practice and Policy' is to understand the kind of stem cell research and treatment being done in India, who is involved in it and how it is being done and place it in the larger context of India's health policy. I would like to explore why stem cell research is important for policy makers, patients/caregivers and clinicians/scientists and to understand the expectations these individuals have of stem cell research.

3. Why would the researcher like to interview you?
For my research study I am conducting semi-structured interviews with scientists/clinicians, policy makers and patients/caregivers. Your experiences with stem cell research and treatment will contribute greatly to our understanding of stem cell treatment in India, who is seeking it, why they are seeking it and how it is being provided. For example, I would like to know how you heard about stem cells and what your expectations are about the potential cures offered by stem cells.

4. Interviewee confidentiality
The names or identities of patients selected for the interview will be strictly confidential.

5. Use of information
The information gathered will be used for academic purposes only and confidentiality of the interviewee will be maintained.

6. Harms involved in participating in the research
The researcher does not anticipate any harm to the patient in the course of the interview.

7. Benefits of research
While there is no direct benefit to the participant such as payment or treatment, the patients personal experiences with providers of stem cell treatment and their hopes and expectations of the treatment is crucial to our understanding of India's stem cell industry. There is very little information about the kind of stem cell treatment and experimentation being conducted in the country, on the kind of people who are seeking it and their reasons for doing so.

8. Voluntary participation
It is your choice whether you want to participate or not and if you choose to not be interviewed then the services being provided to you at this centre will continue and nothing will change.

9. Right to withdraw consent
You can stop the interview at any time even if you had agreed to it earlier. If there is a specific question that causes you any discomfort you can choose to not answer it. I would be glad to conduct the interview at a place of your convenience. With your permission, I would also like to record your interview. If you have any objection please let me know.

Part II:
Certificate of Consent
I have read the information mentioned above or it has been read out to me. I have had the chance to ask questions about it and have been given satisfactory explanations. I consent voluntarily to participate in this study.

Name of participant:

Signature of participant:

Date:

If Illiterate:

Thumbprint of participant:

I have witnessed the consent procedure and I confirm that the individual has given consent freely.

Name of witness 1:

Signature of witness 1:

Name of witness 2:

Signature of witness 2

Date:

Statement by the researcher:
I have explained the patient information sheet to the participant, and to the best of my ability I have made sure that the participant understands the intents and purposes of my study. I confirm that the participant was given a chance to ask me questions about the interview/study and that consent was given freely and voluntarily.

Name of researcher/person taking consent:

Signature of researcher/person taking consent:

Date:

A copy of this document has been given to the participant.
For further contact please see my address given on the previous page.

Informed Consent Form (Caregivers)

Part I:
Information Sheet

1. Information about the researcher
My name is Rohini Kandhari. I am a public health (PhD) student at the Jawaharlal Nehru University (JNU) in New Delhi. My address is:
C/O Centre of Social Medicine & Community Health, School of Social Sciences
Jawaharlal Nehru University, New Mehrauli Road, New Delhi – 110067.

2. Purpose of my study
The purpose of my study, entitled 'Stem Cell Research and Experimentation in India: Mapping Practice and Policy' is to understand the kind of stem cell research and treatment being done in India, who is involved in it and how it is being done and place it in the larger context of India's health policy. I would like to explore why stem cell research is important for policy makers, patients/caregivers and clinicians/scientists and to understand the expectations these individuals have of stem cell research.

3. Why would the researcher like to interview you?
For my research study I am conducting semi-structured interviews with scientists/clinicians, policy makers and patients/caregivers. Your experiences with stem cell research and treatment will contribute greatly to our understanding of stem cell treatment in India, who is seeking it, why they are seeking it and how it is being provided. For example, I would like to know how you heard about stem cells and what your expectations are about the potential cures offered by stem cells.

4. Interviewee Confidentiality
The names or identities of caregivers selected for the interview will be strictly confidential.

5. Use of information
The information gathered will be used for academic purposes only and confidentiality of the interviewee will be maintained.

6. Harms involved in participating in the research
The researcher does not anticipate any harm to the caregiver in the course of the interview.

7. Benefits of research
The research may not benefit you directly, but the caregiver's experiences with providers of stem cell treatment and or research institutions and their hopes and expectations of the treatment/research is crucial to our understanding of India's stem cell industry. There is very little information about the kind of stem cell treatment and experimentation being conducted in the country, on the kind of people who are seeking it and their reasons for doing so.

8. Voluntary participation:
It is your choice whether you want to participate or not and if you choose to not be interviewed then the services being provided to you at this centre will continue and nothing will change.

9. Right to withdraw consent
You can stop the interview at any time even if you had agreed to it earlier. If there is a specific question that causes you any discomfort you can choose to not answer it. I would be glad to conduct the interview at a place of your convenience. With your permission, I would also like to record your interview. If you have any objection please let me know.

Part II:
Certificate of Consent

I have read the information mentioned above or it has been read out to me. I have had the chance to ask questions about it and have been given satisfactory explanations. I consent voluntarily to participate in this study.

Name of participant:

Signature of participant:

Date:

If illiterate:

Thumb print of participant:

I have witnessed the consent procedure and I confirm that the individual has given consent freely.

Name of witness 1:

Signature of witness 1:

Name of witness 2:

Signature of witness 2:

Date:

Statement by the researcher:
I have explained the information sheet to the participant, and to the best of my ability I have made sure that the participant understands the intents and purposes of my study. I confirm that the participant was given a chance to ask me questions about the interview/study and that consent was given freely and voluntarily.

Name of researcher/person taking consent:

Signature of researcher/person taking consent:

Date:

A copy of this document has been given to the participant.
For further contact please see my address given on the previous page.

Informed Consent Form (Policy Makers)

Part I:
Information Sheet

1. Information about the researcher:
My name is Rohini Kandhari. I am a PhD student at the Centre of Social Medicine & Community Health, School of Social Sciences, Jawaharlal Nehru University (JNU) in New Delhi. My address is:
C/O Centre for Social Medicine & Community Health, School of Social Sciences
Jawaharlal Nehru University, New Mehrauli Road, New Delhi – 110067.

2. Purpose of my study
The purpose of my study, entitled 'Stem Cell Research and Experimentation in India: Mapping Practice and Policy' is to understand the kind of stem cell research and treatment being done in India who is involved in it and how it is being done and place it in the larger context of India's health policy. I would like to explore why stem cell research is important for policy makers, patients/caregivers and clinicians/scientists and to understand the hopes and expectations these individuals have of stem cells.

3. Why would the researcher like to interview you?
For my research study I am conducting semi-structured interviews with scientists/clinicians, policy makers and patients/caregivers. Your understanding of India's stem cell industry, of the state's objectives for promoting stem cell research and state policy in science and technology and in stem cells in particular will contribute greatly to my understanding on the subject and to the objectives of my study.

4. Interviewee confidentiality
The names or identities of interviewees and their institutions will be kept strictly confidential.

5. Use of information
The information gathered will be used for academic purposes only.

6. Harms involved in participating in the research
The researcher does not anticipate any harm to the interviewee in the course of the interview.

7. Benefits of research
The research may not benefit you directly but the information you provide will be important for our understanding on India's stem cell industry, of state policy on the subject and future directions for India's stem cell industry. There is very little information about the nature of stem cell research and experimentation being done in the country, why it is being supported and who is seeking it.

8. Voluntary participation
It is entirely your choice whether you want to participate or not in this research study.

9. Right to withdraw consent
Once you have decided to give an interview you have the right to withdraw your consent at any point of time during the study. In the course of the interview if there is a specific question that causes you any discomfort you can choose to not answer it. With your permission, I would also like to record your interview. If you have any objection please let me know.

Part II:
Certificate of Consent

I have read the information mentioned above or it has been read out to me. I have had the chance to ask questions about it and have been given satisfactory explanations. I consent voluntarily to participate in this study.

Name of participant:

Signature of participant:

Date:

Statement by the researcher:
I have explained the information sheet and my research to the participant to the best of my ability. I have made sure that the participant understands the intents and purposes of my study. I confirm that the participant was given a chance to ask me questions about the interview/study and that consent was given freely and voluntarily.

Name of researcher/person taking consent:

Signature of researcher/person taking consent:

Date:

A copy of this document has been given to the participant.

For further contact please see my address given on the previous page:

Informed Consent Form (Clinicians/Scientists)

Part I:
Information Sheet

1. Information about the researcher
My name is Rohini Kandhari. I am a PhD student at the Centre for Social Medicine & Community Health, School of Social Sciences, Jawaharlal Nehru University (JNU) in New Delhi. My address is:
C/O Centre of Social Medicine & Community Health, School of Social Sciences
Jawaharlal Nehru University, New Mehrauli Road
New Delhi – 110067.

2. Purpose of my study
The purpose of my study, entitled 'Stem Cell Research and Experimentation in India: Mapping Practice and Policy' is to understand the kind of stem cell research and treatment being done in India, who is involved in it and how it is being done and place it in the larger context of India's health policy. I would like to explore why stem cell research is important for policy makers, patients/caregivers and clinicians/scientists and to understand the hopes and expectations these individuals have of stem cells.

3. Why would the researcher like to interview you?
For my research study I am conducting semi-structured interviews with scientists/clinicians, policy makers and patients/caregivers. Your experiences with stem cell research and or treatment will contribute greatly to my understanding on the subject and to the objectives of my study.

4. Interviewee confidentiality
The names or identities of interviewees and their institutions will be kept strictly confidential.

5. Use of information
The information gathered will be used for academic purposes only.

6. Harms involved in participating in the research
The researcher does not anticipate any harm to the interviewee in the course of the interview.

7. Benefits of research
The research may not benefit you directly but the information you provide will be important for our understanding of India's stem cell industry. There is very little information about the nature of stem cell research and experimentation being done in the country, why it is being supported and who is seeking it.

8. Voluntary participation
It is entirely your choice whether you want to participate or not in this research study.

9. Right to withdraw consent
Once you have decided to give an interview you have the right to withdraw your consent at any point of time during the study. In the course of the interview if there is a specific question that causes you any discomfort you can choose to not answer it. With your permission, I would also like to record your interview. If you have any objection please let me know.

Part II:
Certificate of Consent

I have read the information mentioned above or it has been read out to me. I have had the chance to ask questions about it and have been given satisfactory explanations. I consent voluntarily to participate in this study.

Name of participant:

Signature of participant:

Date:

Statement by the researcher:
I have explained the information sheet and my research to the participant to the best of my ability. I have made sure that the participant understands the intents and purposes of my study. I confirm that the participant was given a chance to ask me questions about the interview/study and that consent was given freely and voluntarily.

Name of researcher/person taking consent:

Signature of researcher/person taking consent:

Date:

A copy of this document has been given to the participant.

For further contact please see my address given on the previous page:

Appendix C: Interview schedules

1. Patient interview schedule:

1. General background of the patient:

- Age
- Place of Residence
- Occupation
- Family

2. What is the condition you are suffering from?
3. Have you undergone any treatment for it?
4. Where did you receive the treatment?
5. Did you experience any relief/improvement from the treatment?
6. Have you completed the stem cell intervention or are you in the process of it?
7. What kind of stem cell intervention (unproven treatment/trial/pilot study)?
8. What type of stem cells were used?
9. Where did you undergo the stem cell intervention?
10. Did you have to incur any costs for the stem cell intervention?
11. What was the period of the stem cell treatment/trial/pilot study?
12. Why did you decide to try stem cells for your condition (unproven treatment/trial/pilot study)?
13. How did you hear about stem cells?
14. What do you know about stem cells?
15. What did the doctor tell you about stem cells?
16. How did you hear about this clinic/hospital?
17. Did you come to Delhi (site in question) especially for stem cell treatment/trial/pilot study?
18. What do you expect the stem cells will do for your current condition?
19. Would you recommend stem cell treatment/trial/pilot study to others?
20. What is your opinion about stem cell research/treatment in general?
21. What kind of difficulties did you have to face as a result of your health condition?

2. Policy maker interview schedule:

1. What is your institution's/department mandate?
2. Is supporting stem cell research a part of your department's policy agenda? If, so what is the idea behind supporting stem cell research.
3. What kind of stem cell research/projects have you supported or plan to in the future?
4. What is your opinion on the current science of stem cells?
5. How far or near are we from clinical applications?
6. How is the state facilitating stem cell research in India?
7. What was the idea behind the formation of the Department of Biotechnology's stem cell initiative?
8. What is the idea behind the creation of bio-clusters and autonomous institutes?
9. What is the major source of funding for stem cell research in India?
10. What kind of budget does your department have for stem cell research?
11. What is the general nature of India's stem cell industry?
12. In what types of institutions is stem cell research/experimentation taking place in India?
13. What kinds of stem cells are usually used?
14. What are the kind of regulatory procedures and requirements for stem cell research and experimentation in India?
15. Have you been directly involved with the formulation of ethical guidelines on stem cell research?
16. Do you interact with the central/state biotech/science & technology department in any advisory capacity?
17. What should the role of the government be in stem cell research/treatment in India?
18. What in your opinion are the challenges faced by stem cell research in India today?
19. What in your opinion are the challenges faced by Indian science today?
20. How can these challenges be overcome?
21. Where do you see the future for India in stem cell research and treatment?
22. What is your departments/institution's future plan in stem cell research?
23. The state describes the biotechnology sector as the 'Sunshine Sector'. What does that mean?
24. What should India's research priorities be?
25. What role should science & technology play in India today?

3. Clinicians/scientists interview schedule:

1. Why are clinicians/scientists interested in stem cells?
2. What is your opinion on the current science of stem cells?
3. What is your particular interest in stem cells?
4. What kind of stem cell research/trials, if any, have you been specifically involved with at your institution or have facilitated?
5. How far away from or near are we from clinical applications in stem cells?
6. As a doctor, if your patient asked you about stem cells what would you say to them?
7. What kinds of patients participate in your stem cell research/trials?
8. What kind of questions/concerns do patients/families have about stem cells?
9. What kinds of concerns do you have about stem cell research/treatments?
10. Where did your patients hear about stem cells?
11. What was the thinking behind doing stem cell research at your hospital/institution?
12. Where do stem cells fit in the larger picture of research at your hospital/institution?
13. What kind of stem cell research/projects/trials does your institution prefer to undertake?
14. What kind of permissions/ethical guidelines do you have to follow for stem cells?
15. Is stem cell research expensive?
16. What is the major source of funding for stem cell research in India?
17. What is the general nature of India's stem cell 'industry'?
18. Are many stem cell trials being conducted in India? What kind of trials are these?
19. In what types of institutions is stem cell research/experimentation taking place?
20. What kinds of stem cells are usually used?
21. How has the state/govt. facilitated stem cell research/treatment in India?
22. What should the role of the government be in stem cell research in India?
23. What in your opinion are the challenges faced by stem cell research in India?
24. What in your opinion are the challenges faced by Indian science?
25. Where do you see the future for India in stem cell research/treatment?
26. What is your institution's future plan in stem cell research/therapy?
27. What role should science & technology play in India today?

Bibliography and References

1. Ahmed, Sara (2010) *The Promise of Happiness*. Durham: Duke University Press.
2. Alaszewski, Alan and Wilkinson, Iain (2015) 'The Paradox of Hope for Working Age Adults Recovering From Stroke', *Health*, 19(2), pp.172-187.
3. Allen, Pauline and Waters, W.E. (1983) 'Attitudes to research ethical committees', *Journal of Medical Ethics*, 9 (2), pp.61-65.
4. Althusser, Louis (2014) *On the Reproduction of Capitalism: Ideology and Ideological State Apparatuses*. London: Verso.
5. Angell, Marcia (2004) *The Truth About Drug Companies: How They Deceive Us and What to Do About It*. New York: Random House Trade Paperbacks.
6. Arora, Parveen (2005) 'Healthcare Biotechnology Firms in India: Evolution, Structure and Growth', *Current Science*, 89 (3), pp. 458-463.
7. Association of Biotechnology Led Enterprises (2012) *Indian Biotechnology: The Road Map to the Next Decade and Beyond*. New Delhi: DBT, GOI.
8. Australian Stem Cell Centre (2011) *Stem Cell Therapies: Now and in the Future*, available at http://www.stemcellfoundation.net.au, last viewed 7 Dec 2011.
9. Baader, Gerhard *et al.* (2005) 'Pathways to Human Experimentation, 1933-1945: Germany, Japan, and the United States', *Osiris*, 20 (2), pp. 205-231.
10. Baburajan, K (2001) 'Reliance Life Files Provisional Patent in Stem Cells Area', available at http://www.rediff.com, posted 31 Aug, viewed 22 Jan 2018.
11. Baker, Monya (2008) 'James Thomson: Shifts from Embryonic Stem Cells to Induced Pluripotency', *Nature Reports Stem Cells*, available at www.nature.com/stemcells/2008, posted 14 Aug, Viewed 13 Jan 2016.
12. Banta, David H. (1980) 'The Diffusion of the Computed Tomography (CT) Scanner in the United States', *International Journal of Health Services*, 10 (2), pp. 251-269.
13. Barde, Sameer (n.d.) 'Stemming It', *Pune Times, The Times of India*.
14. Baru, Rama (2005) 'Private Health Sector in India-Raising Inequities' in Gangoli, Leena V., Duggal, Ravi and Shukla, Abhay (eds.) *Review of Healthcare in India*. Mumbai: Centre for Enquiry into Health & Allied Themes, pp. 269-277.
15. Baru, Rama V. (1998) *Private Health Care in India: Social Characteristics and Trends*. New Delhi: Sage Publications India Pvt. Ltd.

16. Baru, Rama V. (2000) 'Privatisation and Corporatisation', *Seminar 489,* available at http://www.india-seminar.com/2000/489, viewed 8 Aug 2016.
17. Baru, Rama V. (2006) *Privatisation of Healthcare in India: A Comparative Analysis of Orissa, Karnataka and Maharashtra States*. Dharwar: Centre for Multidisciplinary Development Research (CDMR).
18. Baru, Rama V. (2016) 'Commercialization and the Poverty of Public Health Services in India' in Hodges, Sarah and Rao, Mohan (eds.) *Public Health and Private Wealth*. New Delhi: Oxford University Press, pp. 121-138.
19. Baru, Rama V. (forthcoming 2018) 'Rise of Medical Industry Complex: Trends in Corporatisation of Health Services' in Prasad, Purendra and Jesani, Amar (eds.) *Equity and Access: Health Care Studies*. New Delhi: Oxford University Press.
20. Basu, S. *et al* (2012) 'Comparative Performance of Private and Public Healthcare Systems in Low- and Middle-Income Countries: A Systematic Review', *PLoS Medicine*, 9 (6), pp. 1-14.
21. Basu, Saionton (2006) 'Regulating Stem Cell Research in India: Wedding the Public to Policy', *Current Science*, 90 (11), pp.1476-1479.
22. Baudrillard, Jean (2001) *Selected Writings* (2nd ed.), Cambridge, U.K.: Polity Press.
23. Baviskar, Amita and Ray, Raka (2011) 'Introduction' in Baviskar, Amita and Ray, Raka (eds.) *Elite and Everyman: the Cultural Politics of the Indian Middle Classes*, New Delhi: Routledge, pp. 1-23.
24. Becker, Gay (2000) *The Elusive Embryo: How Women and Men Approach New Reproductive Technologies.* Berkeley: University of California Press.
25. Beecher, Henry K. (1966) 'Ethics and Clinical Research', *The New England Journal of Medicine*, 274 (24), pp. 367-372.
26. Beike Biotechnology (2015) *Stem Cell Therapy Empowers Patient to Pursue Dreams*, available at https://stemcelltreatmentnow.com/stem-cell-therapy-empowers-patient-pursue-dreams, Posted Aug 6 2015, viewed 14 Feb 2017.
27. Beike Biotechnology Co. Ltd (2014) available at www.beikebiotech.com, viewed 4 Feb 2016.
28. Bell, Catherine (2009) *Ritual Theory, Ritual Practice*. New York: Oxford University Press.
29. Bernard, Stan (2002) 'The drug drought: primary causes, promising solutions', *Pharmaceutical Executive*, November, pp.6-10.
30. Bharadwaj, Aditya (2014) 'Experimental Subjectification: The Pursuit of Human Embryonic Stem Cells in India', *Ethnos: Journal of Anthropology*, 79 (1), pp.

84-107.

31. Bharadwaj, Aditya and Glasner, Peter (2009) *Local Cells, Global Science: The Rise of Embryonic Stem Cell Research in India*. London: Routledge.
32. Bhattacharjee, Yudhijit (2008) 'India Hopes New Fellowships Will Attract Expat Scientists', *Science*, 312 (5895), p.1431.
33. Birch, Kean (2006) 'The Neoliberal Underpinnings of the Bioeconomy: The Ideological Discourses and Practices of Economic Competitiveness', *Genomics, Society and Policy*, 2 (3), pp.1-15.
34. Birch, Kean (2009) 'The Knowledge-Space Dynamic in the UK Bioeconomy', *Area*, 41 (3), pp. 273-284.
35. Bisht, Ramila, Pitchforth, Emma and Murray, Susan F. (2012) 'Understanding India, Globalisation and Health Care Systems: A Mapping of Research in the Social Sciences', *Globalization and Health*, 8 (32), pp. 1-15.
36. Bisserbe, Noemie (2010) 'A Shot in the Dark', *Business World*, available at http://www.businessworld.in, viewed 18 Mar 2013.
37. Blume, Stuart S. (1992) *Insight and Industry*, Cambridge, Massachusetts: The MIT Press.
38. Blume, Stuart S. (2013) 'Medical Innovations: Their Diffusion, Adoption, and Critical Interrogation', *Sociology Compass*, 7(9), pp. 726-737.
39. Borup, Mads *et al.* (2006) 'The Sociology of Expectations in Science and Technology', *Technology Analysis and Strategic Management*, 18 (3/4), pp. 285-298.
40. Bosk, Charles L. (1999) 'Professional Ethicist Available: Logical, Secular, Friendly', *Daedalus*, 128 (4), pp.47-68.
41. Bound, Kirsten (2007) *India: The Uneven Innovator*. London: Demos.
42. Brock, Gary (1990) 'Ritual and Vulnerability', *Journal of Religion and Health*, 29 (4), pp.285-295.
43. Brown, Nik (2000) 'Organising/Disorganising the Breakthrough Motif: Dolly the Cloned Ewe Meets Astrid the Hybrid Pig' in Brown, Nik, Rappert, Brian and Webster, Andrew (eds.) *Contested Futures: A Sociology of Prospective Techno-science*. Ashgate Publishing Ltd., pp. 87-110.
44. Brown, Nik (2003) 'Hope Against Hype – Accountability in Biopasts, Presents and Futures', Science Studies, 16 (2), pp.3-21.
45. Brown, Nik (2005) 'Shifting Tenses: Reconnecting Regimes of Truth and Hope', *Configurations*, 13 (3), pp. 331-355.
46. Brown, Nik and Michael, Mike (2002) 'From Authority to Authenticity: The Changing Governance of Biotechnology', *Health, Risk & Society*, 4 (3), pp.

259-272.

47. Brown, Nik and Michael, Mike (2003) 'A Sociology of Expectations: Retrospecting Prospects and Prospecting Retrospects', *Technology Analysis & Strategic Management*, 15 (1), pp. 3-18.
48. Brown, Nik and Webster, Andrew (2004) *New Medical Technologies and Society: Reordering Life*. Cambridge, U.K.: Polity Press Ltd.
49. Brown, Nik, Kraft, Alison and Martin, Paul (2006) 'The Promissory Pasts of Blood Stem Cells', *BioSocieties*, 1 (3), pp.329-348.
50. Brown, Nik, Rappert, Brian and Webster, Andrew (2000) 'Introducing Contested Futures: From *Looking Into* the Future to *Looking at* the Future' in Brown, Nik, Rappert, Brian and Webster, Andrew (eds.) *Contested Futures: A Sociology of Prospective Techno-science*. Ashgate Publishing Ltd., pp.3-20.
51. Butler, Judith (1997) *The Psychic Life of Power: Theories in Subjection*. Stanford: Stanford University Press.
52. Campbell, Timothy C. (2011) *Improper Life: Technology and Biopolitics from Heidegger to Agamben*. Minneapolis: University of Minnesota Press.
53. Cancer Research UK (2014) *Granulocyte Colony Stimulating Factor* (G-CSF), available at http://www.cancerresearchuk.org, posted 4 Aug, viewed 18 Jan 2018.
54. CenterWatch Online (2017) *Report: Global Clinical Trial Service Market Will Reach $64B By 2020,* available at https://www.centerwatch.com/news-online, posted 8 Feb, viewed 18 Jan 2018.
55. Chakravarthi, Indira (2014) 'Medical Technology: Review and a Test of Perspectives', *Nehru Memorial Museum and Library* (*NMML) Occasional Paper: Perspectives in Indian Development,* 26.
56. Chaturvedi, Sachin (2005) 'Dynamics of Biotechnology Research and Industry in India: Statistics, Perspectives and Key Policy Issues'*, OECD Science, Technology and Industry Working Papers 2005/06.* Paris: Organisation for Economic Co-operation and Development Publishing, available at http://dx.doi.org/10.1787/873577115356, viewed 23 Sep 2012.
57. Chen, Haidan and Gottweis, Herbert (2013) 'Stem Cell Treatments in China: Re-thinking the Patient Role in the Global Bio-Economy', *Bioethics*, 27 (4), pp.194-207.
58. Chengappa, Raj (2010) 'How Stem Cells Can Save Your Life', *India Today*, 25 Jan, pp. 48-56.
59. Choon-Piew, Pow (2009) *Gated Communities in China*: *Class, Privilege and the Moral Politics of the Good Life*. London: Routledge.

60. Clarke, Adele E. *et al* (2003) 'Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine', *American Sociological Review*, 69 (2), pp. 161-194.
61. Clinical Trial Registry of India, National Institute of Health Statistics (2016), available at www.ctri.nic.in, viewed 21 Dec 2016.
62. Cohen, Lawrence (2004) 'Surgery at the Margin of the State', in Das, Veena and Poole, Deborah (eds.) *Anthropology in the Margins of the State*. Santa Fe: School of American Research Press. Oxford: James Currey Ltd., pp.165-190.
63. Cohen, Lawrence (2005) 'Operability, Bioavailability, and Exception' in Ong, A., Collier and J. Stephen (eds.) *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems*. Blackwell Publishing Ltd., pp.79-90.
64. Conrad, Peter (2007) *The Medicalization of Society*: *On the Transformation of Human Conditions into Treatable Disorders*. Baltimore: The John Hopkins University Press.
65. Cooper, Melinda (2008) *Life as Surplus: Biotechnology and Capitalism in the Neoliberal Era*. Seattle: University of Washington Press.
66. Cooper, Melinda (2012) 'The Pharmacology of Distributed Experiment–User Generated Innovation', *Body & Society*, 18 (3&4), pp. 18-43.
67. Cote, Stephane (2011) 'How Social Class Shapes Thoughts and Actions in Organizations', *Research in Organizational Behavior*, 31, pp. 43-71.
68. Creditor, Morton C. and Garrett, Julie Beetle (1977) 'The Information Base for Diffusion of Technology: Computed Tomography Scanning', *The New England Journal of Medicine*, 297 (1), pp. 49-52.
69. Crespo, Carla *et al*. (2013) 'Family Routines and Rituals in the Context of Chronic Conditions: A Review', *International Journal of Psychology*, 48 (5), pp. 729-746.
70. Datta, Bishakha and Misra, Geetanjali (2000) 'Advocacy for Sexual and Reproductive Health', *Reproductive Health Matters*, 8 (16), pp. 24-34.
71. De Vries, Raymond G. and Forsberg, Carl P. (2002) 'What do IRBs look like? What kind of support do they receive?', *Accountability in Research*: *Policies & Quality Assurance*, 9 (3-4), pp. 199-216.
72. Department of Biotechnology and Indian Council of Medical Research, Government of India (2007) *Guidelines for Stem Cell Research and Therapy*. New Delhi: ICMR.
73. Department of Biotechnology and Indian Council of Medical Research, Government of India (2007) *Guidelines for Stem Cell Research and Therapy*. New Delhi: ICMR.

74. Department of Biotechnology, Government of India (2006) *Report of the Working Group on Biotechnology for the Eleventh Five Year Plan* (*2007-2012),* available at http://www.dst.gov.in, viewed 16 Jan 2018.
75. Department of Biotechnology, Government of India (2006), Biotech News, available at http://www.biotechnews.gov.in, viewed 1 Aug 2013.
76. Department of Biotechnology, Government of India (2008) *Biotechnology Industry Partnership Programme*, available at http://www*.dbtindia.nic.in/BIRAP/BIPP%20-%20Proposal%20Submission.pdf,* viewed 3 Sep 2012.
77. Department of Biotechnology, Government of India (2009-2010) *Annual Report*, available at http://www.dbtindia.nic.in, viewed 19 Aug 2012.
78. Department of Biotechnology, Government of India (2011) *Report of the Working Group on Biotechnology 12th Plan* (*2012-2017),* available at: http://www.planningcommission.nic.in/aboutus/../sandt/wg_dbt2905.pdf*,* viewed 15 Sept 2012.
79. Department of Biotechnology, Government of India (n.d.) *National Biotechnology Development Strategy*, available at http://www.dbtindia.nic.in, viewed 19 Aug 2012.
80. Department of Biotechnology, Government of India (n.d.), *Vision*, available at http://www.dbtindia.nic.in, viewed 19 Aug 2012.
81. Department of Health, Government of India (2013) *The Drugs and Cosmetics (Amendment) Bill 2013*, available at www.prsindia.org, viewed 1 Mar 2018.
82. Department of Health, Government of India, *The Drugs and Cosmetics Act, 1940*, *The Drugs and Cosmetics Rules, 1945*. Delhi: Commercial Law Publishers.
83. Department of Information Technology, Biotechnology and Science & Technology, Government of Karnataka, *The Millennium Biotech Policy II*, available at http://www.bangaloreitbt.in, viewed 23 Sep 2012.
84. Department of Science & Technology, Science Advisory Council to the Prime Minister (2010) *India as a Global Leader in Science*. New Delhi: DST
85. Deshpande, Satish (2006) 'Mapping the 'Middle': Issues in the Analysis of the Non-Poor' Classes in India', in John, Mary E., Jha, Praveen Kumar and Jodhka, Surinder S. (eds.) *Contested Transformations*: *Changing Economies and Identities in Contemporary India*, New Delhi: Tulika Books, pp. 215-236.
86. Devitt, Terry (2008) *Research on Human Embryonic Stem Cells Marks 10-year Milestone*, available at http//www.wtnnews.com/articles/5199, last viewed 10 December 2017.

87. Dhar (2014) *ICMR Redefines Stem Cell Use to Curb Malpractice*, available at: http://www.thehindu.com/sci-tech/health/medicine-and-research/icmr-redefines-stem-cell-use-to-curb malpractice, viewed 24 Feb 2014.
88. Dickenson, Donna (2008) *Body Shopping: Converting Body Parts to Profit*. Oxford, England: Oneworld Publications.
89. Dowie, Mark, Ehrenreich, Barbara and Minkin, Stephen (1979) 'The Charge: Gynocide, The Accused: The U.S. Government', *Mother Jones*, Nov-Dec, available at http://motherjones.com, viewed 23 Jan 2018.
90. Drennan, Kathleen B. (2003) 'Pharma wants you: clinical trials are agencies' new proving ground', *Pharmaceutical Executive*, April, pp. 82-87.
91. Duggal, Ravi (2001) *Evolution of Health Policy in India*. Available at www.cehat.org/cehat/uploads/files/a147.pdf, viewed 20 Mar 2015.
92. Duggal, Ravi (2005) 'Historical Review of Health Policy Making', in Gangoli, Leena V., Duggal, Ravi and Shukla, Abhay (eds.) *Review of Healthcare in India*. Mumbai: Centre for Enquiry into Health & Allied Themes, pp. 21-40.
93. Duggal, Ravi and Gangoli, Leena V. (2005) 'Introduction to Review of Healthcare in India', in Gangoli, Leena V., Duggal, Ravi and Shukla, Abhay (eds.) *Review of Healthcare in India*. Mumbai: Centre for Enquiry into Health & Allied Themes, pp. 3-18.
94. Edge, David (1995) 'Reinventing the Wheel' in Jasonoff, Sheila *et al*. (eds.) *Handbook of Science and Technology Studies*. Los Angeles, Calif.: Sage Publications, pp.3-23.
95. Einsiedel, E.F. and Adamson, H. (2012) 'Stem Cell Tourism and Future Stem Cell Tourists: Policy and Ethical Implications', *Developing World Bioethics*, 12 (1), pp. 35-44.
96. Engelke, Mathew (2002) 'The Problem of Belief: Evans-Pritchard and Victor Turner on "The Inner-Life" ', *Anthropology Today*, 18 (6), pp.3-8.
97. Ernst & Young (2011) *Beyond Borders: Global Biotechnology Report 2011*. Ernst & Young.
98. Eurenius, K. *et al* (1997) 'Perception of Information, Expectations and Experience Among Women and Their Partners Attending a Second-Trimester Routine Ultrasound Scan', *Ultrasound in Obstetrics and Gynecology*, 9, pp.86-90.
99. Fernandes, Leela (2000) 'Nationalizing 'the Global': Media Images, Cultural Politics and the Middle Class in India', *Media, Culture & Society*, 22 (5), pp. 611-628.
100. Fernandes, Leela (2006) *India's New Middle Class: Democratic Politics in an*

Era of Economic Reform. Minneapolis: University of Minnesota Press.

101. Fernandes, Leela (2011) 'Hegemony and Inequality: Theoretical Reflections on India's 'New' Middle Class' in Baviskar, Amita and Ray, Raka (eds.) *Elite and Everyman: the Cultural Politics of the Indian Middle Classes*, New Delhi: Routledge, pp. 58-82.
102. Fernandes, Leela and Heller, Patrick (2006) 'Hegemonic Aspirations', *Critical Asian Studies*, 38 (4), pp. 495-522.
103. Filly, Roy A. and Crane James P. (2002) 'Routine Obstetric Sonography', *Journal of Ultrasound in Medicine*, 21 (7), pp. 713-718.
104. Fineberg, Harvey V. (1979) 'Gastric Freezing-A Study of Diffusion of a Medical Innovation', in National Research Council and Institute of Medicine, *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology.* Washington, D.C.: National Academy of Sciences, pp. 173-200.
105. Fineberg, Harvey V. and Hiatt, Howard H. (1979) 'Evaluation of Medical Practices: the Case for Technology Assessment', *New England Journal of Medicine*, 301 (20), pp. 1086-1091.
106. Flick, Uwe (2014) 'Mapping the Field' in Flick, Uwe (ed.) *The Sage Handbook of Qualitative Data Analysis*. Los Angeles: Sage Publications Ltd, pp.3-18.
107. Foucault, Michael (1982) 'The Subject and Power', *Critical Inquiry*, 8 (4), pp. 777-795.
108. Foucault, Michel (2001) *Madness and Civilization: A History of Insanity in the Age of Reason*. London: Routledge.
109. Franklin, Sarah (1997) *Embodied Progress: A Cultural Account of Assisted Conception*. London: Routledge.
110. Franklin, Sarah (2001) 'Culturing Biology: Cell Lines for the Second Millennium', *Health*, 5(3), pp.335-354.
111. Franklin, Sarah (2005) 'Stem Cells R Us: Emergent Life Forms and the Global Biological' in Ong, A., Collier and J. Stephen (eds.) *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems*. Blackwell Publishing Ltd., pp.439-463.
112. Franklin, Sarah (2013) *Biological Relatives: IVF, Stem Cells, and the Future of Kinship*. Durham: Duke University Press.
113. Franklin, Sarah and McNeil, Maureen (1988) 'Review: Reproductive Futures: Recent Literature and Current Feminist Debates on Reproductive Technologies', *Feminist Studies*, 14 (3), pp. 545-560.
114. Frew, Sarah E. *et al*. (2007) 'India's Health Biosector at a Crossroads', *Nature*

Biotechnology, 25 (4), pp.403-417.

115. Friedman, S. Laurie and Marcovitz, Hal (2009) '*Is Stem Cell Research Necessary*? San Diego: Referencepoint Press.
116. Gardner, Richard (2005) ' Don't Stem this Tide', *The Times of India*, 24 May, p. 16.
117. Geertz, Clifford (1973) *The Interpretation of Cultures: Selected Essays*. New York: Basic Books, Inc.
118. Giddens, Anthony (1991) *Modernity and Self-Identity: Self and Society in the Late Modern Age*. Stanford: Stanford University Press.
119. Giddens, Anthony (1999) 'Risk and Responsibility', *The Modern Law Review*, 62 (1), pp.1-10.
120. Gieryn, Thomas F. (2000) 'A Space for Place in Sociology', *Annual Review of Sociology*, 26 (2000) pp.463-496.
121. Glasner, Peter (2009) 'Cellular Division: Social and Political Complexity in Indian Stem Cell Research', *New Genetics and Society*, 28 (3), pp. 283-296.
122. Gomes-Gupta, Sheree (2005) 'Celling Hope: A Breakthrough', *The Times of India*, 22 Jan, p. A3.
123. Good, Mary-Jo Delvecchio (2001) 'The Biotechnical Embrace', *Culture, Medicine and Psychiatry*, 25 (4), pp.395-410.
124. Good, Mary-Jo Delvecchio *et al* (1990) 'American Oncology and the Discourse on Hope', *Culture, Medicine and Psychiatry*, 14 (1), pp. 59-79.
125. Gooptu, Nandini (2009) 'Neoliberal Subjectivity, Enterprise Culture and New Workplaces: Organised Retail and Shopping Malls in India', *Economic and Political Weekly*, 44 (22), pp. 45-54.
126. Gordon George, S.J. (1956) 'The Sociology of Ritual', *The American Catholic Sociological Review*, 17 (2), pp.117-130.
127. Gottweis, Herbert, Salter, Brian and Waldby, Catherine (2009) *The Global Politics of Human Embryonic Stem Cell Science: Regenerative Medicine in Transition*. London and New York: Palgrave and Macmillan.
128. Government of Karnataka (n.d.) *Sector Profile: Biotechnology*, available at *164.100.52.24/pdf/karnataka/Sector%20Profiles/BT.pdf*, viewed 10 Jan 2013.
129. Hacking, Ian (2012) 'Introductory Essay' in Kuhn, Thomas S. (4th ed), *The Structure of Scientific Revolutions*. Chicago: Chicago University Press, pp. vii-xivi.
130. Hammersley, Martyn (2006) 'Ethnography: Problems and Prospects', *Ethnography and Education*, 1(1), pp. 3-14.
131. Hanefeld, J. *et al* (2015) 'Why do Medical Tourists Travel to Where They do?

The Role of Networks in Determining Medical Travel', *Social Science & Medicine*, 124 (Jan), pp. 356-363.

132. Harvey, Alison (2009) 'From Genetic Risk to Post-genomic Uncertainties: Nutrigenomics and the "Birth of the Genetic Entrepreneur" ', *New Genetics and Society*, 28 (2), pp. 119-137.
133. Harvey, Alison (2010) 'Genetic Risks and Healthy Choices: Creating Citizen Consumers of Genetic Services Through Empowerment and Facilitation', *Sociology of Health & Illness*, 32 (3), pp. 365-381.
134. Hayenhjelm, Madeleine (2006) 'Out of the Ashes: Hope and Vulnerability as Explanatory Factors in Individual Risk Taking', *Journal of Risk Research*, 9(3), pp.189-204.
135. Herman, Edward S. and Chomsky, Noam (1988) *Manufacturing Consent: The Political Economy of the Mass Media*: New York: Pantheon Books.
136. Hodges, Sarah (2012) ' "It All Changed After Apollo": Healthcare Myths and their Making in Contemporary India', *Indian Journal of Medical Ethics*, X (4), pp.242-249.
137. Hodges, Sarah (2012) 'On the Limits to Speculative Surplus Value: Cord Blood Banking in Chennai', *Workshop on Science, Technology and Medicine in Modern India*, Jawaharlal Nehru University, Delhi, 23 Mar.
138. Hodges, Sarah (2013) 'Umbilical Cord Blood Banking and its Interruptions: Notes From Chennai, India', *Economy and Society*, 42 (4), pp. 1-20.
139. Hoffman, Sharona (2000) 'Beneficial and unusual punishment: an argument in support of prisoner participation in clinical trials', *Indiana Law Review*, 33 (2), pp. 475-515.
140. Holborow, Marnie (2007) 'Language, Ideology and Neoliberalism', *Journal of Language and Politics*, 6:1 (2007), pp.51-73.
141. Hopkins, Michael M. *et al* (2007) 'The Myth of the Biotech Revolution: An Assessment of Technological, Clinical, and Organisational Change', *Research Policy*, 36 (4), pp. 566-589.
142. Horwitz, Rainey (2018) 'The Dalkon Shield', *The Embryo Project Encyclopedia*, available at http://embryo.asu.edu, posted 10 Jan, viewed 23 Jan 2018.
143. Hostiuc, Sorin *et al* (2016) 'Translational Research—the Need of a New Bioethics Approach', *Journal of Translational Medicine*, 14 (16) pp. 1-10.
144. Illich, Ivan (1976) *Medical Nemesis: The Expropriation of Health*. New York: Pantheon Books.
145. India Brand Equity Foundation (2017) *Healthcare*, posted Dec 2017, available at http://www.ibef.org/industry/healthcare, viewed 1.1.2018.

146. *India Today Online* (2012) 'Full Text of PM's Speech at Indian Science Congress', available at http://indiatoday.intoday.in/story/mannmohan-singh-china, posted 3 Jan, viewed 26 Mar 2012.
147. Indian Council of Medical Research (n.d.) *List of Enrolled Reproductive Technology (ART) Clinics Under National Registry of ART Clinics and Banks in India*, available at www.icmr.nic.in, viewed 25 Feb 2018.
148. Indian Council of Medical Research & Department of Biotechnology, Government of India (2013) *National Guidelines for Stem Cell Research*. New Delhi: ICMR.
149. Indian Council of Medical Research & Department of Biotechnology, Government of India (2017) *National Guidelines for Stem Cell Research*. New Delhi: ICMR.
150. Indian Council of Medical Research, Government of India (2006) *Ethical Guidelines for Biomedical Research on Human Participants*. New Delhi: ICMR.
151. Institute of Stem Cell Biology and Regenerative Medicine, Government of India, available at: http://www.instem.res.in, viewed 26 April 2017.
152. Jansonn, Bengt (1998) *Controversial Psychosurgery Resulted in a Nobel Prize*, available at: https://www.nobelprize.org, viewed 2 Jan 2018.
153. Jasonoff, Sheila (2004) 'Ordering Knowledge, Ordering Society' in Jasonoff, Sheila (ed.) *States of Knowledge: The Co-production of Science and Social Order*, London: Routledge, pp. 13-45.
154. Jasonoff, Sheila (2005) *Designs on Nature: Science and Democracy in Europe and the United States*, Princeton: Princeton University Press.
155. Jasonoff, Sheila (2006a) *Experiments Without Borders: Biology in the Labs of Life*, available at http://www.lse.ac.uk/publicEvents, viewed 25 April 2015.
156. Jasonoff, Sheila (2006b) 'Biotechnology and Empire: The Global Power of Seeds and Science', *Osiris*, 21 (1), pp. 273-292.
157. Jawaharlal Nehru Centre for Advanced Scientific Research (2008) *JNCASR Scientists Derive Human Embryonic Stem Cells from Discarded Embryos*, available at http://www.jncasr.ac.in/newsview.php?id=51, posted 25 Aug, viewed 22 Sep 2012.
158. Jayaraman, K.S. (2004) 'Outsourcing Clinical Trials to India Rash and Risky, Critics Warn' *Nature Medicine*, 10 (5), p. 440.
159. Jayaraman, K.S. (2005) 'Indian Regulations Fail to Monitor Growing Stem- Cell Use in Clinics', *Nature*, 434 (17) p.259.
160. Jeffery, Patricia and Jeffery, Rogers (2008) " 'Money Itself Discriminates'": Obstetric Emergencies in the Time of Liberalisation', *Contributions to Indian*

Sociology, 42 (1), pp.59-91.

161. Jeffery, Roger (1979) 'Recognizing India's Doctors: The Institutionalization of Medical Dependency, 1918-39', *Modern Asian Studies*, 13 (02), pp. 301-326.
162. Jesani, Amar (2009) 'Ethics in Ethics Committees: Time to Share Experiences, Discuss Challenges and Do a Better Job', *Indian Journal of Medical Ethics* 6 (2), pp.62-63.
163. John, Mary E. *et al* (2009) 'Dispensing with Daughters: Technology, Society, Economy in North India', *Economic and Political Weekly*, 44 (15), pp.16-19.
164. Joseph, Reji K. (2016) *Pharmaceutical Industry and Public Policy in Post-reform India*. New Delhi: Routledge.
165. Kahn, Jennifer (2006) 'A Nation of Guinea Pigs', *Wired,* available at http://www.wired.com/wired/archive/14-03/indiadrug.html, viewed 18 June 2011.
166. Kamdar, Seema I. (2004) 'Sion Hospital to Begin Stem Cell Research: Doctors Will Focus on Treatment for Spinal Cord Injuries', *The Times of India*, 29 Dec, p. 3.
167. Kandhari, Rohini (2013) 'Justice in Jeopardy: A Qualitative Study of Institutional Ethics Committees in New Delhi', *Indian Journal of Medical Ethics*, 10 (3), pp.176-182.
168. Kaull, Vividha (2005) 'AIIMS Pioneers Stem Cell Injection', *The Times of India*, available at http://timesofindia.indiatimes.com, posted Feb 24, viewed 31 Jan 2018.
169. Kaur, Ravinder (2015) *Tackling India's 'bare branches'*, available at: http://www.india-seminar.com/2015/665/665_ravinder_kaur.htm, viewed 25 Dec 2017.
170. Kearney, A.T. (2006) 'Make your move: taking clinical trials to the best location', *Executive Agenda*, 9 (1), pp.56-62, available at http://www.atkearney.com, viewed 2 Aug 2010.
171. Kearns, Robin A. and Barnett, Ross J. (1997) 'Consumerist Ideology and the Symbolic Landscapes of Private Medicine', *Health & Place*, 3 (3), pp.171-180.
172. Kehoe, Louise (1976) 'Battle for the X-ray Scanner Market', *New Scientist*, 25 November, p. 457-458.
173. Kent, Julie *et al*. (2006) 'Culturing Cells, Reproducing and Regulating the Self', *Body & Society*, 12 (1), pp. 1-23.
174. Koch, Lene and Stemerding, Dirk (1994) 'The Sociology of Entrenchment: A Cystic Fibrosis Test for Everyone?', *Social Science & Medicine*, 39 (9), pp. 1211-1220.
175. Koenig, Barbara A. (1988) 'The Technological Imperative in Medical Practice:

The Social Creation of a "Routine" Treatment' in Lock, Margaret and Gordon, Deborah (eds.) *Biomedicine Examined*. Dordrecht: Kluwer Academic Publishers, pp. 465-496.

176. Koleva, Gregana (2012) 'Embryonic Stem Cells and an Underlying Lure for the Ill, CNN Doc Shows', *Forbes*, available at https://forbes.com, posted 21 May, viewed 2 Feb 2018.
177. Lakshmi, Rama (2001) 'India Plans to Fill Void in Stem Cell Research', *The Washington Post*, available at https://www.washingtonpost.com, posted 28 Aug, viewed 22 Jan 2018.
178. Lefebvre, Bertrand (2008) 'The Indian Corporate Hospitals: Touching Middle Class Lives', in Jaffrelot, Christopher and Veer, Peter Van Der (eds.) *Pattern of Middle Class Consumption in India and China*, New Delhi: Sage Publications India, pp. 88-109.
179. Lemke, Thomas (2011) *Biopolitics: An Advanced Introduction*. New York: New York University Press.
180. Lente, Harrow Van (2000) 'Forceful Futures: From Promise to Requirement' in Brown, Nik, Rappert, Brian and Webster, Andrew (eds.) *Contested Futures: A Sociology of Prospective Techno-science*. Ashgate Publishing Ltd., pp. 43-63.
181. Levine, Robert J. (1988) *Ethics and regulation of clinical research* (2nd ed.), Connecticut: Yale University Press.
182. Levine, Robert J. (2001) 'Institutional Review Boards: A Crisis in Confidence', *Annals of Internal Medicine*, 134 (2), pp. 161-163.
183. LifeCell (2015) *Indian Stem Cell Technology Receives Patent to Treat Incurable Diseases*, available at https//www.lifecell.in, posted 7 Aug, viewed 28 Dec 2017.
184. Lock, Margaret (1988) 'Introduction', in Lock, Margaret and Gordon, Deborah (eds.) *Biomedicine Examined*. Dordrecht: Kluwer Academic Publishers, pp.3-10.
185. Lock, Margaret (1996) 'Displacing Suffering: The Reconstruction of Death in North America and Japan', *Daedalus*, 25 (1), pp.207-244.
186. Lofgren, Hans and Benner, Mats (2010) 'A Global Knowledge Economy? Biopolitical Strategies in India and the European Union', *Journal of Sociology*, 47 (2), pp.163-180.
187. Lown, Bernard (2007) *The Commodification of Health Care*, available at http://www.pnhp.org/publications/the_commodification_of_health_care.php, viewed 8 May 2017.
188. Mahal, Varshney and Taman (2006) 'Diffusion of Diagnostic Medical Devices and Policy Implications for India', *International Journal of Technology*

Assessment in Healthcare, 22 (2), pp.184-190.

189. Majumdar, P.K. (2005) *Research Methods in Social Science*. New Delhi: Viva Books Private Limited.
190. Mandel, Ernest (2002) 'Anticipation and Hope as Categories of Historical Materialism', *Historical Materialism*, 10 (4), pp.245-259.
191. Marshall, Eliot (1998) 'A Versatile Cell Line Raises Scientific Hopes, Legal Questions', *Science*, 282 (5391), pp.1014-1015.
192. Martin, Paul, Brown, Nik and Kraft, Alison (2008) 'From Bedside to Bench? Communities of Promise, Translational Research and the Making of Blood Stem Cells', *Science as Culture*, 17 (1), pp. 29-41.
193. Martin, Paul, Brown, Nik and Turner, Andrew (2008) 'Capitalizing Hope: the Commercial Development of Umbilical Cord Blood Stem Cell Banking, *New Genetics and Society*, 27 (2), pp. 127-143.
194. May, Carl and Finch, Tracy (2009) 'Implementing, Embedding and Integrating Practices: An Outline of Normalization Process Theory', *Sociology*, 43(3), pp.535-554.
195. McMichael, Megan and Shipworth, David (2013) 'The Value of Social Networks in the Diffusion of energy-efficiency innovations in UK Households', *Energy Policy*, 53 (Feb) pp.159-168.
196. Miller, Peter and Rose, Nikolas (2008) *Governing the Present*, Cambridge U.K.: Polity Press Ltd.
197. Ministry of Science & Technology, Government of India, (2007) *Government Accords Approval to the National Biotechnology Development Strategy*, available at http://www.pib.nic.in/release/rel_print_page.asp?relid=32628, posted 13 Nov, viewed 27 Nov 2012.
198. Ministry of Science and Technology, Government of India (2013) *Science, Technology and Innovation Policy 2013*. New Delhi.
199. Mirowski and Van Horn (2005) 'The Contract Research Organization and the Commercialization of Scientific Research', *Social Studies of Science*, 35 (4), pp. 503-548.
200. Misztal, Barbara A. (2002) 'Rethinking the Concept of Normality: The Criticism of Comte's Theory of Normal Existence', *Polish Sociological Review*, 138 (2002), pp.189-202.
201. Mol, Annemarie (2010) 'Freedom or Socks - Market Promises versus Supportive Care in Diabetes Treatment' in Patton, Cindy (ed.) *Rebirth of the Clinic: Places and Agents in Contemporary Healthcare*. Minneapolis: University of Minnesota Press, pp. 99-120.

202. Moniz, Egas (1937) 'Prefrontal Leucotomy in the Treatment of Mental Disorders', '*The American Journal of Psychiatry*', 93 (6), pp.1379-1385.
203. Moreira, Tiago and Palladino, Paolo (2005) 'Between Truth and Hope: On Parkinson's Disease, Neurotransplantation and the Production of the 'Self'', *History of the Human Sciences*, 18 (3), pp. 55-82.
204. Morrison, Michael and Cornips, Lucas (2012) 'Exploring the Role of Dedicated Online Biotechnology News Providers in the Innovation Economy', *Science, Technology & Human Values*, 37 (3), pp. 262-285.
205. Mulkay, Michael (1993) 'Rhetorics of Hope and Fear in the Great Embryo Debate', *Social Studies of Science*, 23 (4), pp. 721-42.
206. Murdoch, Charles E. and Scott, Christopher Thomas (2010) 'Stem Cell Tourism and the Power of Hope', *The American Journal of Bioethics*, 10 (5), pp.16-23.
207. National Institutes of Health, U.S. (2016) *Stem Cell Information*, available at http://stemcells.nih.gov/info/basics, viewed 24 Aug 2012.
208. National Research Council and Institute of Medicine (1979) *Medical Technology and the Health Care System: A Study of the Diffusion of Equipment-Embodied Technology.* Washington, D.C.: National Academy of Sciences.
209. Novas, Carlos (2006) 'The Political Economy of Hope: Patients' Organizations, Science and Biovalue', *BioSocieties*, 1 (3), pp.289-305.
210. Novas, Carlos and Rose, Nikolas (2000) 'Genetic Risk and the Birth of the Somatic Individual', *Economy and Society*, 29 (4), pp.485-513.
211. Nundy, Samiran and Gulhati, Chandra M. (2005) 'A New Colonialism? — Conducting Clinical Trials in India', *The New England Journal of Medicine*, 352 (16), pp. 1633-1636.
212. Ong, Aihwa (2010) 'An Analytics of Biotechnology and Ethics at Multiple Scales', in Ong, Aihwa and Chen Nancy N. (eds.) *Asian Biotech: Ethics and Communities of Fate*. Durham: Duke University Press. pp.1-51.
213. Pandya, Sunil K. (2008) 'Stem Cell Transplantation in India: Tall Claims, Questionable Ethics', *Indian Journal of Medical Ethics*, 5 (1), pp. 15-17.
214. Park, Alice (2011) *The Stem Cell Hope: How Stem Cell Medicine Can Change Our Lives*. New York: Hudson Street Press.
215. Parveen, Jahanara (2009) 'Stem Cells, The Future Therapy', *BioSpectrum*, available at https://biospectrumindia.com, posted 10 Mar, viewed 2 Feb 2018.
216. Patel (2016) 'Drugs and Cosmetics Bill in the Works' http://www.business-standard.com/article/economy-policy/drugs-and-cosmetics-bill-in-the-works-116062300011_1.html, posted June 23, viewed 17 Jan 2017

217. Patra Prasanna K. and Sleeboom-Faulkner, Margaret (2016) 'Following the Banking Cycle of Umbilical Cord Blood in India: the Disparity between Pre-banking Persuasion and Post-banking Utilization', *New Genetics and Society*, 35 (3), pp. 267-288.
218. Patra, Prasanna K. and Sleeboom-Faulkner, Margaret (2009) 'Bionetworking: Experimental Stem Cell Therapy and Patient Recruitment in India', *Anthropology & Medicine*, 16 (2), pp.147-163.
219. Petersen, Alan and Seear, Kate (2011) 'Technologies of Hope: Techniques of the Online Advertising of Stem Cell Treatments', *New Genetics and Society*, 30 (4), pp. 329-346.
220. Petersen, Alan, Seear, Kate and Munsie, Megan (2013) 'Therapeutic Journeys: The Hopeful Travails of Stem Cell Tourists', *Sociology of Health & Illness*, 36 (5), pp.670-685.
221. Petryna, Adriana (2005) 'Drug Development and the Ethics of the Globalized Clinical Trial', *Occasional Paper*, Oct 22, pp. 1-25.
222. Petryna, Adriana (2007) 'Experimentality: On the Global Mobility and Regulation of Human Subject Research', *PoLAR*, 30 (2), pp.288-304.
223. Petryna, Adriana (2009) *When Experiments Travel*: *Clinical Trials and the Global Search for Human Subjects*. Princeton: Princeton University Press.
224. Pinch, Trevor J. and Bijker, Wiebe E. (1987) 'The Social Construction of Facts and Artifacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other', in Bijker, Wiebe E, Hughes, Thomas P. and Pinch, Trevor (eds.) *New Directions in the Sociology and History of Technology*. Cambridge, Massachusetts: The MIT Press, pp.17-50.
225. Poster, Mark (2001) 'Introduction' in Poster (ed.) *Baudrillard, Jean, Selected Writings*, Cambridge, U.K.: Polity Press, pp. 1-9.
226. Prasad, Amit (2015) 'Ambivalent Journeys of Hope: Embryonic Stem Cell Therapy in a Clinic in India', *Health*, 19 (2), pp. 137-153.
227. Press Information Bureau, Government of India (2016) *Withdrawal of the Drugs and Cosmetics (Amendment) Bill, 2013*, available at http://pib.nic.in/newsite/PrintRelease, posted 22 June, Viewed 1 Mar 2018.
228. Qadeer, Imrana (2000) 'Health Care Systems in Transition III. India, Part I. The Indian Experience', *Journal of Public Health Medicine*, 22 (1), pp.25-32.
229. Qadeer, Imrana (2010) *New Reproductive Technologies and Health Care in Neo-Liberal India: Essays*. New Delhi: Centre for Women's Development Studies.
230. Qadeer, Imrana (2011) *Public Health in India: Critical Reflections*, Critical

Public Health Series No. I. Delhi: Daanish Books.

231. Qadeer, Imrana and Reddy, Sunita (2013) 'Medical Tourism in India: Perceptions of Physicians in Tertiary Care Hospitals', *Philosophy, Ethics and Humanities*, 8 (20), pp.1-10.
232. Raaj, Neelam (2005) 'Hope Cells: Wide Angle', *The Times of India*, 16 Oct, p.9.
233. Rabinow, Paul (1984) *The Foucault Reader*. New York: Pantheon Books.
234. Ramesh, Randeep (2005) *Row Over Doctor's 'Miracle Cures'* https://www.theguardian.com/science/2005/nov/18/stemcells.controversiesinscience? posted 18 Nov, viewed 31 Dec 2017.
235. Ranganathan, Maya (2015) 'The Mediated Nation in the Age of Globalisation' in Rodrigues, Usha M. and Ranganathan, Maya (eds.) *Indian News Media: From Observer to Participant*. New Delhi: Sage Publications, pp.175-202.
236. Rao, Mohan (2004) *From Population Control to Reproductive Health: Malthusian Arithmetic.* New Delhi: Sage Publications Pvt. Ltd.
237. Rao, Mohan (2017) Comments at the release of the book, Ravinder Kaur (ed.) *Too Many Men Too Few Women: Social Consequences of Gender Imbalance in India and China.* New Delhi:Orient Blackswan, at the India International Centre, 9 Feb, New Delhi.
238. Ravi, Shamika (2017) 'Restructuring the Medical Council of India to Eliminate Corruption', *LiveMint*, available at http://www.livemint.com, posted 19 Sep, viewed 21.1.2018.
239. Ravindran, Deapica and Ingle, Girish (2010) 'Clinical trials in India: the needs of the country and the focus of sponsors' in proceedings of the *3rd National bioethics conference*, New Delhi, 17- 20 November.
240. Ravindran, Deapica and Nikarge, Sachin (2010) 'Clinical trials watch', *Indian Journal of Medical Ethics*, 7 (4), pp.259-262.
241. Reliance Life Sciences (2009) *Cord Blood Repository*, available at http://www.rellife.com, viewed 17 Jan 2018.
242. Ritu Priya (2005) 'Public Health Services in India: A Historical Perspective', in in Gangoli, Leena V., Duggal, Ravi and Shukla, Abhay (eds.) *Review of Healthcare in India*. Mumbai: Centre for Enquiry into Health & Allied Themes, pp.41-74.
243. Robinson, Andrew (2011) *An A-Z of Theory Arjun Appadurai*, available at http://ceasefiremagazine.co.uk, posted 22 April, viewed 14 Jan 2018.
244. Rodrigues, Usha M. (2015) 'Introduction: Indian News Media in a Globalised Era', in Rodrigues, Usha M. and Ranganathan, Maya (eds.) *Indian News*

Media: From Observer to Participant. New Delhi: Sage Publications, pp.1-33.

245. Rose, Nikolas (2001) 'The Politics of Life Itself', *Theory, Culture & Society*, 18 (6), pp.1-30.
246. Rose, Nikolas (2007) *The politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century*. Princeton: Princeton University Press.
247. Rose, Nikolas and Novas, Carlos (2005) 'Biological Citizenship' in Ong, A., Collier, J. Stephen (eds.) *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems*. Blackwell Publishing Ltd., pp.439-463.
248. Sahu, S.K. (1981) *Health Culture of the Oraons in the Context of Different Health Institutions*, Ph.D. Thesis Submitted to the Jawaharlal Nehru University. New Delhi: CSMCH.
249. Saini, Anu (2016) 'Physicians of Colonial India (1757-1900)', *Journal of Family Medicine and Primary Care*, 5(3), pp.528-532.
250. Saldana, Johnny (2008) *The Coding Manual for Qualitative Researchers*. Los Angeles, Calif.: Sage Publications Ltd.
251. Salter, Brian (2009) 'State Strategies and the Geopolitics of the Global Knowledge Economy: China, India and the Case of Regenerative Medicine', *Geopolitics* 14 (1) pp. 47-78.
252. Salter, Brian and Salter, Charlotte (2007) 'Bioethics and the Global Moral Economy: The Cultural Politics of Human Embryonic Stem Cell Science', *Science, Technology & Human Values*, 32 (5), pp.554-581.
253. Salter, Brian *et al*. (2007) 'Stem Cell Science in India: Emerging Economies and the Politics of Globalization', *Regenerative Medicine*, 2 (1), pp. 75-89.
254. Sama-Resource Group for Women and Health (2008) 'Assisted Reproductive Technologies: Autonomy or Subjugation? A Case Study From India', *Women's Studies International Forum*, pp.319-325.
255. Sampat, Bhaven N. (2010) 'Lessons from Bayh-Dole', *Nature*, 468 (7325), pp. 755-756.
256. Sarojini, N. *et al* (2011) 'Undeniable Violations and Unidentifiable Violators', *Economic & Political Weekly*, XLVI (24), pp.17-19.
257. Sarojni, Nadimpally, Marwah, Vrinda and Shenoi, Anjali (2011) 'Globalisation of Birth Markets: a Case Study of Assisted Reproductive Technologies in India', *Globalisation and Health*, 7 (27), pp. 1-9.
258. Sathyamala C. (2000) *An Epidemiological Review of the Injectable Contraceptive, Depo-Provera*, Pune: Medio Friends Circle & Forum for Women's Health.
259. Schnepel, Burkhard (1987) 'Max Weber's Theory of Charisma and its

Applicability in Anthropological Research', *Journal of the Anthropological Society of Oxford*, 18 (1), pp.26-48.

260. Scudellari, Megan (2011) 'A Decade of iPS Cells', *Nature*, 534 (7607), pp.310-312.
261. Selvarajan, Sandhiya *et al* (2013) 'Clinical Trials in India: Where Do We Stand Globally?', *Perspectives in Clinical Research*, 4 (3), pp. 160-164.
262. Sengupta and Nundy (2005) 'The Private Health Sector in India', *British Medical Journal*, 331 (7528) pp.1157-58.
263. Sengupta, Amit (2013) 'Universal Health Care in India: Making it Public, Making It a Reality', *Occasional Paper*, 19 (May). The Municipal Services Project.
264. Sexton, Sarah (2011) 'The Future is Now: Genetic Promises and Speculative Finance' in *Global Health Watch 3:An Alternative World Health Report*. London: Zed Books, pp. 199-210.
265. Shapiro, Stephan and Schwan, Anne (2011) *How to Read Foucault's Discipline and Punish*. London: Pluto Press.
266. Sharp, Rachel (1982) 'Self-contained Ethnography or a Science of Phenomenal Forms and Inner Relations', *The Journal of Education*, 164 (1), pp.48-63.
267. Shukla, Sonal (2009) 'Banking on Stem Cells', *Express Healthcare*, available at http://healthcare.financialexpress.com/200905/market01.shtml, viewed 5 Dec 2012.
268. Singh, Seema (2001) 'Stem Cell Primer', *The Times of India*, 25 Sep, p. 10.
269. Sinha, Kounteya (2013) '1st Human Liver Made From Stem Cells: Breakthrough May Pave Way for Ending Critical Shortage of Donor Organs', *The Times of India,* 5 Jul, p.21.
270. Sleeboom-Faulkner, Margaret and Patra, Prasanna Kumar (2011) 'Experimental Stem Cell Therapy: Biohierarchies and Bionetworking in Japan and India', *Social Studies of Science*, 41(5), pp.645-666.
271. Smith, Sara (2014) 'Intimate Territories and the Experimental Subject in Ladakh, India', *Ethnos*, 79 (1), pp. 41-62.
272. Society of Regenerative Medicine and Tissue Engineering (SRMTE) (2013), Proceedings of the Ninth Annual Conference on Biotechnology, Bengaluru, Jan 31-Feb 1 2013.
273. Srinivasan, Sandhya (2006) 'Rogue Research in the Guise of Stem Cell Therapy', *InfoChange,* available at http//www.infochangeindia.org, posted Mar, viewed 7 Mar 2012.
274. Srinivasan, Sandhya (2009) *Ethical Concerns in Clinical Trials in India: An*

Investigation. Mumbai: Centre for Studies in Ethics and Rights (CSER).

275. Srivastava, Anupam (2017) *Private Healthcare with Public Money*, available at http://www.live mint.com. posted 25 Jul, viewed 15 Jan 2018.
276. Srivastava, Sanjay (2015) *Entangled Urbanism: Slum, Gated Community, and Shopping Mall in Delhi and Gurgaon*. New Delhi: Oxford University Press.
277. Stempeutics Research (2016) Press Release, available at http://www.stempeutics.compdf/05-2016-PressRelease-Stempeucel-Approval-in-India.pdf, viewed 17 Jan 2018.
278. Stern, Megan (2006) 'Dystopian Anxieties Versus Utopian Ideals: Medicine from Frankenstein to the Visible Human Project and Body Worlds', *Science as Culture*, 15 (01), pp.61-84.
279. Sturgeon, David (2014) 'The Business of the NHS: the Rise and Rise of Consumer Culture and Commodification in the Provision of Healthcare Services', *Critical Social Policy*, 34 (3), pp. 405-416.
280. Sunder Rajan, Kauhsik (2006) *Biocapital: The Constitution of Postgenomic Life*. Durham: Duke University Press.
281. Sunder Rajan, Kaushik (2005) 'Subjects of Speculation: Emergent Life Sciences and Market Logics in the United States and India', *American Anthropologist*, 107 (1), pp.19-30.
282. Sunder Rajan, Kaushik (2007) 'Experimental Values: Indian Clinical Trials and Surplus Health', *New Left Review*, 45 (May-June), pp. 67-88.
283. Tach, Laura and Cornwell, Benjamin (2015) 'Social Networks and Social Capital: New Directions for a Household Panel Survey', *Journal of Economic and Social Measurement*, 40, pp. 249-281.
284. Taussig, Karen-Sue, Rapp, Rayna and Heath, Deborah (2005) 'Flexible Eugenics: Technologies of the Self in the Age of Genetics' in Inda, Jonathan Xavier (ed.) *Anthropologies of Modernity: Foucault, Governmentality, and Life Politics*. Oxford, U.K.: Blackwell Publishing, pp. 194-212.
285. Thatte, Urmila M. and Marathe, Padmaja A. (2017) 'Ethics Committees in India: Past, Present and Future', *Perspectives in Clinical Research*, 8 (1), pp. 22-30.
286. *The Economic Times* (2015) 'Indian Medical Tourism Industry to Touch $ 8 Billion by 2020', available at http://www.economictimes.indiatimes, posted Nov 2015, viewed 1 Jan 2018.
287. *The Times of India* (1999) 'The Promise of Stem Cells', 20 July, p. A8.
288. *The Times of India* (2001) 'Asia May Lead the Way in Stem Cell Research', 26 Dec, p.9.
289. *The Times of India* (2001) 'Experts Claim Breakthrough in Stem Cell Research',

17 Aug, p.11.

290. *The Times of India* (2005) 'Breakthrough in Stem Cells: They Can Be Tailored for Patients MADE TO ORDER', 21 May, p. 21.
291. *The Times of India* (2006) 'Trend Trackers I Health: Stem Cells Move Closer to Reality', 3 Jan, p. 31.
292. Thiers, Fabio A., Sinskey, Anthony J. and Berndt, Ernst R. (2008) 'Trends in the globalization of clinical trials', *Nature Reviews Drug Discovery*, 7 (1), pp.13-14.
293. Thompson, Charis (2005) *Making Parents: The Ontological Choreography of Reproductive Technologies*. Cambridge, MA: MIT Press.
294. Thompson, Charis (2010) 'Asian Regeneration? Nationalism and Internationalism in Stem Cell Research in South Korea and Singapore' in Ong, Aihwa and Chen N. Nancy (eds.) *Asian Biotech: Ethics and Communities of Fate.* Durham and London: Duke University Press. pp.95-117.
295. Thompson, Charis (2013) *Good Science: the Ethical Choreography of Stem Cell Research*, Cambridge, Massachusetts: The MIT Press.
296. Thompson, Peter (2013) 'Introduction: The Privatization of Hope and the Crisis of Negation' in Thompson, Peter and Zizek, Slavoj (eds.) *The Privatization of Hope: Ernst Bloch and the Future of Utopia*, pp. 1-20.
297. Thomson, James A. *et al* (1998) 'Embryonic Stem Cell Lines Derived from Human Blastocysts', *Science*, 282 (5391), pp. 1145-47.
298. Thorold, Crispin (2001) 'Indian Firms Embrace Biotechnology', *BBC News*, available at http://www.news.bbc.co.uk, posted 6 Apr, viewed 27 Mar 2012.
299. Times News Network (2001), 'Indian Stem Lines to be Part of Research', *The Times of India*, 11 Aug, p.12.
300. Times News Network (2002) 'Stem Cell Therapy has its Limitations, Says Scientist', *The Times of India*, 29 July, p.12.
301. Times News Network (2005) 'Ramadoss Provides Blue Print for Stem Cell Research', *The Times of India*, 19 Sep p.8.
302. Times News Network (2005) 'Stem Cells Are the New Age Gene', *The Times of India*, 14 May, p.6.
303. Towghi, Fouzieyha and Vora, Kalindi (2014) 'Bodies, Markets, and the Experimental in South Asia', *Ethnos: Journal of Anthropology*, 79(1), pp.1-18.
304. Tyfield, David (2010) 'Neoliberalism, Intellectual Property and the Global Knowledge Economy' in Birch, K. and Mykhnenko, V. (eds.) *The Rise and Fall of Neoliberalism: The Collapse of an Economic Order*. London and New York: Zed Books, pp.60-76.

305. Unistem (2015) available at www.unistembiosciences.com, viewed 25 Jan 2016.
306. Valenstein, Elliot S. (1986) *Great and Desperate Cures: The Rise and Decline of Psychosurgery and other Radical Treatments*. New York: Basic Books, Inc.
307. Vanac, Mary (2009) *PricewaterhouseCoopers Puts a Number on Personalized Medicine Market: $ 232 Billion*, available at http://medcitynews.com/2009, posted 8 Dec, viewed 1 Feb 2018.
308. Vogel, Gretchen (1999) 'Capturing the Promise of Youth', *Science*, 286 (5448) pp.2238-2239.
309. Vora, Kalindi (2013) 'Potential, Risk, and Return in Transnational India Gestational Surrogacy', *Current Anthropology*, 54 (7) pp.97-106.
310. Wade, Nicholas (2010) *A Decade Later, Genetic Map Yields Few New Cures*, available at http://www.nytimes.com, posted 12 June, viewed 15 Jan 2018.
311. Waitzkin, Howard (1989) 'A Critical Theory of Medical Discourse: Ideology, Social Control, and the Processing of Social Context in Medical Encounters', *Journal of Health and Social Behaviour*, 30 (June), pp. 220-239.
312. Waldby, Catherine (2002) 'Stem Cells, Tissue Cultures and the Production of Biovalue', *Health,* 6 (3) pp.305-323.
313. Waldby, Catherine (2012) 'Medicine: The Ethics of Care, the Subject of Experiment', *Body & Society*, pp.179-192.
314. Waldby, Catherine and Cooper, Melinda (2008) 'The Biopolitics of Reproduction', *Australian Feminist Studies*, 23 (55), pp.57-73.
315. Webb, Darren (2013) 'Pedagogies of Hope' *Studies in Philosophy and Education*, 32 (4) pp.397-414.
316. Webster, Andrew (2002) 'Innovative Health Technologies and the Social: Redefining Health, Medicine and the Body', *Current Sociology*, 50 (3), pp.443-457.
317. Whittaker, A (2008) 'Pleasure and Pain: Medical Travel in Asia', *Global Public Health: An International Journal for Research, Policy and Practice*, 3 (3), pp.271-290.
318. Williams, Raymond (1980) *Problems in Materialism and Culture*. London: Verso.
319. Wilson-Kovacs, Dana M. and Hauskeller, Christine (2012) 'The Clinician-scientist: Professional Dynamics in Clinical Stem Cell Research', *Sociology of Health and Illness,* 34 (4), pp. 497-512.

320. Wilson, Duncan (2011) ‘Creating the ‘ethics industry’: Mary Warnock, in vitro fertilization and the history of bioethics in Britain’, *BioSocieties*, 6 (2), pp. 121-141.
321. Wilson, Paul and Rao, Aarthi (2012) *India’s Role in Global Health R & D.* Washington DC: The Results for Development Institute.
322. World Medical Association (2013) ‘Declaration of Helsinki: Ethical Principles for Medical Research’, *JAMA*, 310 (20), pp. 2191-2194.
323. Zimmermann, Rainer E. (2013) ‘Transforming Utopian into Metopian Systems: Bloch’s Principle of Hope *Revisited*’ in Thompson, Peter and Zizek, Slavoj (eds.) *The Privatization of Hope: Ernst Bloch and the Future of Utopia*, pp. 246-268.
324. Zola, Irving. K (1975) ‘In the Name of Health and Illness: On Some Socio-political Consequences of Medical Influence’, *Social Science and Medicine*, 9, pp. 83-87.
325. 100 Dreams (2014) available at www.100Dreams.in on Behance posted 15 April, viewed 2 Jan 2018.