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On the Everyday Ethics of Stem Cell Therapies in India

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Introduction

> The doctor just stopped coming to see us. We were in the hospital, but they didn't want us there, so they started pretending like we weren't there. So we came here, as the doctors and therapists come to us, and we know they care about me…and my recovery.
>
> *(Bukeshwar.[1] Translated from Marathi, based on Dec 2015 interview notes)*

The above quote is from a 20-year-old male patient who had travelled to Mumbai from a rural part of Maharashtra. When interviewed, he was in a hospital that specialised in autologous stem cell therapy[2]

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and was about to receive his first transfers later that day. At the age of 16, he started experiencing rapid muscle loss and was diagnosed with Limb-Girdle Muscular Dystrophy (LGMD). He went from being able to walk and bicycle to school to being completely bedridden, unable to walk around the house without the help of a family member. Bukeshwar, an articulate young man, expressed multiple frustrations with his experience of medical treatment. Among these was the number of times he had been moved between specialists and hospitals, and the exorbitant fees his family had paid for private health care in India.[3] When Bukeshwar's family arrived in Mumbai for his treatment, they found that hospital after hospital was unable or unwilling to treat his condition. Additionally, they never had a physician who took the time to fully explain the disease or its prognosis to them. When Bukeshwar was finally admitted to a neurological ward in a leading private hospital, physicians there were initially willing to spend time attempting to find a cure or a way to stall the progress of his muscle failure. However, a few weeks after his arrival, they withdrew due to the lack of a promising prognosis and eventually stopped coming to see him altogether.

Bukeshwar felt that he and his family were never given any concrete information regarding his condition or the potential for a cure. At this stage, Bukeshwar's uncle told the family about a 'stem cell hospital'[4] that could help with muscular dystrophy. Although the family was not certain about the efficacy of stem cell therapies for LGMD, Bukeshwar searched on the Internet (although he was digitally savvy, his parents were just functionally literate) and decided he wanted to give this therapy a try. After being largely ignored by hospital doctors, Bukeshwar spent a week in a clinical setting with constant attention and supervision. Unlike his previous experiences, the medical staff engaged him in detailed conversations about his condition. Consequently, rather than seeing stem cell therapy as their last option, he and his family wished they had pursued it earlier.

After hearing similar stories about medical practices in India and spending almost 2 years in and out of various sites providing stem cell therapy, Bukeswhar's account was a reminder to the researchers that the imposition of a universalist ethics of stem cell research and therapy may not be useful for understanding the medical and everyday worlds within which stem cells operate in places like India. Instead, in this chapter, we argue for a

new bioethics that is cognisant of local realities alongside global scientific expectations for the future of stem cell research and therapy in India. For our analysis, we draw in particular on Veena Das's concept of 'ordinary ethics', in which she says, 'unless we can come to grips with the everyday life within which moral and ethical questions may be grounded for clinicians, patients, and policymakers, there is little use in debating the relevance of bioethics for low-income countries' (Das 1999: 100). Das contends that even as academic and policy initiatives aim to 'include questions of ethics in non-Western countries', it is only by understanding the everyday that we can hope to work towards a bioethics fit for an evolving global biomedicine. We suggest that a new bioethics should draw on experiences and expectations of local Indian patients seeking and having undergone stem cell therapies, and that it should acknowledge the internal, familial and societal contradictions patients grapple with, in addition to financial burdens. Further, we advocate for a bioethics that draws on the state, not only to fund and regulate, but also to ensure treatment and dignity for people with rare and orphaned diseases. We contend that our approach goes beyond a techno-regulatory framework aimed solely at creating pliable subjects for global stem cell research and therapies.

Methods

The data in this chapter draw on over 2 years of fieldwork in India. This includes multiple semi-structured interviews with 102 interlocutors to create a 'thick description'—a detailed, nuanced, and textured account of the respondents' understanding of and relationships with stem cell research and therapy. It involved talking with patients over cups of *chai* as they prepared for or recovering from stem cell therapy for various diseases and injuries, including spinal cord injuries, Duchenne Muscular Dystrophy (DMD), LGMD, autism, cerebral palsy, intellectual disability, diabetes, arthritis, and optic atrophy. This chapter focuses on local Indian patients and is underpinned by a larger research project, which is informed by interviews and meetings with clinicians, policymakers, researchers, lawyers, and pharmaceutical-company representatives that constitute about 50% of the interviews and interactions.

The entire project is supported by a European Research Council (ERC) grant (#313769). In this chapter, all names have been changed to preserve confidentiality, as per the ethical protocols at the Graduate Institute of International and Development Studies, Geneva, and the European FP7 framework guidelines. All respondents were informed about the nature of the research project and their ability to withdraw at any point from the study. The research ethics clearance exercise, in and of itself, was instructive in framing how the authors thought about ethics in biomedical research. Moreover, in committing to spend extensive time at the sites of their analysis, the authors have refrained from what might be termed 'parachute anthropology'—where a few days are spent collecting large numbers of interviews without a commitment to understanding the textured setting of the everyday. It is in this everyday understanding of biomedicine in India that we aim to situate a call for nuanced understanding of everyday bioethics vis-à-vis stem cells.

The research writing here is based on extensive fieldwork from October 2013 through December 2015 in India, where the authors moved and lived for the duration of the project. Based locally in Delhi, the first author, Appleton, travelled to places across India to map out the stem cell research and therapy terrain in India. The cities where fieldwork was conducted include Pune, Mumbai, Hyderabad, Bangalore, Chennai, Vadodara, Delhi, and the suburbs of Noida and Gurgaon. In each of these locations, participant observations were conducted in multiple sites, including large multi-specialty hospitals in urban hubs and small labs and clinics in smaller cities. The ethnographic data (that is, interviews, researchers' field notes about their impressions and experiences, etc.) were organised and key themes were identified while Appleton was still in India. This served two purposes—to thematically group the data being collected and to see whether certain issues being raised by the interlocutors were missing from the interview protocol. The key themes identified in this chapter were drawn from responses to questions about the government's role in stem cell therapeutics and the ethics of stem cell therapies for local patients. Both Bharadwaj (Bharadwaj and Glasner 2009) and Appleton (Sheoran 2012) have written about their insider/outsider status while conducting fieldwork in India. Although they are both originally from India, they have lived

outside of it for extensive periods of time. This positionality has allowed them to develop the empirical realities evident in the data with a subtle understanding of how bioethics are lived, articulated, rejected, and reconfigured by differently positioned stakeholders in India.

Bioethics in a Local Reality

Since its inception, the 'bioethics enterprise', termed by Arthur Kleinman (1999), has been a project that has garnered critique from analysts within the social sciences in general and anthropology in particular. The critique of the 'bioethics enterprise' ranges from the focus on instrumentalising ethics within medical practices (e.g. prioritising the importance of consent forms and informed consent to the detriment of patient care in medicine, as documented by Corrigan (2003) and Corrigan et al. (2009)), to its potential foreclosure of discussion regarding the changing social, economic, and political realities in divergent local settings that impact bioethics (Thompson 2013: 24). Within critical social-scientific traditions, there has been a dogged effort to account for not only the ethics of medicine, but also the ethics of bioethics narratives and discourse (Bosk 2001; Kleinman 1995: 41–67). This conversation takes on added salience in the context of increased global trade in medical and pharmaceutical sectors, and as parent organisations commit to research that is designed to cause 'no harm' to participants in global settings. In this changing climate, research and practice are expected to meet particular (*Western*) standards—otherwise the potential for harm and exploitation would be too great (Bosk 1999; Muller 1994).

Although well intentioned, the quest to implement global standards and best practices assumes that a Western model of bioethics should and could be replicated universally (see Corrigan 2004). The underlying assumption is that it is better to protect participants and research subjects from unscrupulous medical and clinical practitioners than to let local norms be the guiding principles. Bioethics committees, set up in multinational pharmaceutical corporations and leading research hospitals, therefore work to assure local constituents and shareholders that ethics frameworks are in place to ensure non-exploitation of

research participants and to ensure that globally established parameters are instituted as premier protectors for non-Western populations. In this respect, the 'one-size-fits-all' model of bioethics is not only problematic; it ironically fails the vulnerable populations it seeks to protect.

Early work by Das emphasising the importance of the 'everyday' has been further developed in terms of the notion of 'ordinary ethics'. Das explains what she means by the term as follows:

> I will argue for a shift in perspective from thinking of ethics as made up of judgments we arrive at when we stand away from our ordinary practices to that of thinking of the ethical as a dimension of everyday life in which we are not aspiring to escape the ordinary but rather descend into it as a way of becoming moral subjects. Such a descent into the ordinary does not mean that no attempt is being made to work on this ordinary in the sense of cultivating critical attitudes towards one's culture as it stands, and also working to improve one's conditions of life but that such work is done and not by orienting oneself to transcendental, objectively agreed-upon values but rather through the cultivation of sensibilities *within* the everyday. (2012: 134)

This commitment to locate the ordinary everyday, before arriving at a new bioethics *for* the everyday, drives our work on issues surrounding stem cell research and therapies as these new biotechnologies expand globally.

Anticipatory Moment: Before Regulation, After Guidelines

The local and global media narratives about Indian stem cell therapy clinics and hospitals range from stories of miracles and malpractice to highlighting the reality of those patients who are unable to access medical care for 'orphaned diseases'. Beyond the hype and hyperventilation lies the larger story of how local patients from all socio economic backgrounds experience and engage with the state, medical establishments, and the bioethics of stem cell therapeutics. It can be said that there is

something particular, and yet not extraordinary about *doing* stem cell therapies in India. Somatic cells (that is, all kinds of adult stem cells in the body) are sought to replace human embryonic stem cells (hESC) for a host of scientific applications. As such they represent the new frontier in personalised regenerative medicine. If induced pluripotent stem cells (iPSCs) derived from adult cells can be as efficacious as hESCs, then the need for cell derivation from embryos (which, due to different origin of life perspectives, are ethically fraught entities) will decline (Krimsky 2015: 75–79). While hESCs are important research tools, iPSCs are seen as ethically safer to work with and easier to promote for effective therapeutic applications on a global scale.

Proponents of somatic cells view them as potential cures for conditions ranging from diabetes and autism to spinal cord injury. Nevertheless, there has been significant criticism around issues of safety, efficacy, cost, and the ethics of these stem cell therapies and products in both academia and health-policy circles (Bharadwaj 2012; Cattaneo and Corbellini 2014; Fukuyama 2002; Lauritzen 2005; Ong and Chen 2010). Within the social sciences, ethical panic around embryonic stem cells is being replaced with a much more nuanced understanding of how stem cells are shaping the future of regenerative medicine and society overall (Bharadwaj 2008, 2013a; Franklin 2006, 2007, 2013; Thompson 2013). In this literature, anthropologists are unpacking questions of everyday ethics, of a new biomedical reality where patients cite free will and the right to choose their medical treatment, even those deemed 'experimental', when other options fail (see Bharadwaj 2013a).

In India, hESC and somatic cells are established therapeutic options. In this chapter, we focus on the therapeutic applications of minimally manipulated adherent bone marrow cells (ABMCs). In informal conversations during the explanatory phase of our research project, practising physicians told the first author that some clinics and physicians were using mesenchymal stem cells (MSCs) derived from iPSCs (iPSC–MSC),[5] and some were using bone marrow-derived MSCs (BM–MSCs). The first author's fieldwork in Hyderabad, Mumbai, and Bangalore made evident that research labs and facilities deriving MSCs from iPSCs continue to conduct lab-based research, animal testing, and clinical trials, but that they hoped to see the introduction of a regulatory framework for

applications which have been primarily theoretical thus far. Some of their clinical trials are listed in global clinical studies databases like clinicaltrials.gov (the US clinical trial database) and ctri.nic.in (India's Clinical Trial Registry). However, the patients and physicians included in this chapter are from clinics that, since 2014, have only worked with ABMCs; that is, patients' own biological material returned to their bodies.

The clinics offering stem cell therapies have been working with ABMCs rather than iPSC–MSCs as a result of national guideline changes. These guidelines are not yet regulations, and in the absence of a regulatory law they serve as indicators of best practice, ensuring that practitioners remain informed of developments in the field and practice therapies within the state's purview. In December 2013, the Indian Council for Medical Research (ICMR), under the aegis of the Department of Health Research and Department of Biotechnology, issued an updated National Guidelines for Stem Cell Research (Indian Council for Medical Research 2013). This document updates the ICMR's 2007 guidelines. One of the key differences is the use of the word 'therapy', which is not an oversight but a key point made by the regulatory authorities, and is stated as such in the guidelines:

> Accordingly, any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine, and not offering it as therapy. In accordance with this stringent definition, every use of stem cells in patients outside an approved clinical trial shall be considered as malpractice. It is hoped that this clear definition will serve to curb the malpractice of stem cell 'therapy' being offered as a new tool for curing untreatable diseases. (Indian Council for Medical Research 2013: ii)

Although these guidelines are well intentioned, they offer a framework in which the ICMR is only responsible for stem cell-based research and not therapeutic applications. In the absence of any law, these guidelines suggest that stem cell therapy outside the context of a clinical trial could be considered malpractice. The regulation of cell therapies would thus fall to the Drug Comptroller General of India's purview, since both

clinical trials and prospective drug development would require his office's approval. The stem cell material of an individual (autologous stem cell transfers) would be sold back to that individual as a drug, following a long scientific–bureaucratic chain of phase I through IV clinical trials.[6] However, as these are guidelines rather than regulations, there remains an opportunity to engage in a productive conversation about bioethics at the local level. The clinics providing ABMCs, and the patients receiving them, can continue to do so while making the case they were legally receiving their own material as therapy. Of course, if these guidelines become regulation, then this human biological material becomes a product and ABMC therapies will be illegal.

It is this liminal space that we call the 'anticipatory moment,' before regulations are constituted but after guidelines have been issued, that the global bioethical schema can be reimagined. The regulatory and bioethical guidance framework in India, like the science driving stem cell innovations and their therapeutic applications, has been in a state of continuous evolution. While some scholarship has critiqued the current moment as a 'regulatory vacuum' in Asian countries (Faulkner et al. 2006; Hara et al. 2014; Salter 2008; Tiwari and Desai 2011; Tiwari and Raman 2014; Vertes et al. 2015), we suggest that this moment is a potential space for examining the everyday complexities of doing stem cell research and therapies in India. This 'anticipatory moment', where different stakeholders practice, wait, or critique the applicability of global bioethics for stem cell therapies in India, allows us to imagine a new, more inclusive bioethics. This moment makes visible conversations that may be stifled once regulations are in place, as local voices ask for a bioethics that is cognisant of its Western genealogy, but also accounts for the ways in which biomedicine and biotechnologies are lived, experienced, and engaged with in other global spaces.

Anticipatory Moment: Cost of Care

In addition to the 'regulatory vacuum is an ethical breach' narrative, there has been a focus on improving bioethics around stem cells by focusing on the costs (both material and immaterial) that drive

patients to seek out so-called experimental treatments.[7] In other words, concerns about the experimental nature of stem cell technologies and their high-cost therapeutic application in the absence of proper ethical frameworks have been key for the Indian governmental authorities and global scientific and academic scholarship. This concern is justifiable, as patients' well-being and rights must be placed first when imagining the future of regenerative medicine. Concerns around stem cell therapies in India focus on therapies being offered in non-clinical trial settings at high financial costs. The financial aspects of patient negotiations (with physicians and/or clinics) for stem cell treatments are clearly visible, which on one level is disturbing; however, this visibility gives us an opportunity to examine the ethics around stem cells in India. This is a time where regulatory bodies have not created a universal cost outline for stem cell treatments, nor is therapy only available under clinical trial settings. This then is an anticipatory moment, a liminal space where patients pay for therapies, but along a price gradient determined by their personal circumstances.

During the course of this research, the price for therapeutic treatment ranged from Rs. 70,000 to Rs. 300,000 (USD $1400–$6000), based on need and ability to pay. Additionally, the cost of treatment, while offered at a standardised price within a clinic, differed along two separate lines between clinics. First, clinics in bigger cities like Delhi and Mumbai had higher costs attached to treatments versus smaller cities like Hyderabad or Bangalore. Second, bigger clinics and hospitals, with larger staff and newer technologies, had higher costs compared to smaller clinics or individual physicians doing procedures in larger hospitals. However, this differential price mapping is not exclusive to stem cell-related medical treatments; rather, all private medical care in India is organised along these parameters. However, it is noteworthy that even within an individual clinic or hospital, performing stem cell therapies based on a fixed price—oftentimes the patients' income, economic precarity, and necessity of treatment—leads to lower than advertised charges. The higher charges often included additional services such as room and board for families. Multiple patients who were interviewed received therapies funded by a charity. Although the costs for stem cell

treatments are seemingly high, they are similarly priced to treatments offered in private hospitals and clinics for other specialised care. Further, financial negotiations with physicians and clinics reflect and replicate the same modality in the non-stem cell medical world in India, where direct appeals to physicians alongside conversations through someone with *jaan-pheechan* (familiarity with hospital staff or the organisation) are common. Patients freely spoke about how much they paid for their treatments and their negotiations. In the absence of regulatory frameworks that sanitise or organise the cost factors around the therapeutics framework, the clinics realise there is no need to divert funds or creatively categorise them to make research and therapy permissive. This visibility lends itself to a conceptualisation of the 'regulatory vacuum' as a space in transition where it is easy to identify, categorise, and perhaps correct the economics that drive scientific breakthroughs.

Some scholars continue to speak of India as an ethically problematic space due to the lack of regulatory oversight, rather than critiquing the process and product of regulatory bodies for biomedicine and biotechnologies. The constant articulations of the exploitation of patients by 'local mavericks' obfuscate the fact that, in regulating the stem cell industry, the state is working to create an environment more conducive to global investment in India, which creates another level of bioethical quandaries. In our work, we have instead used this moment of regulatory ambiguity as a nodal point of analysis, where drawing on patient's experience of stem cell therapies allows us to imagine a new bioethics. As will be shown, patient interviews reflect key emerging ideas about patient's expectations vis-à-vis bioethics for stem cell therapies. Patients and patient advocates (often, family members) grapple with internal and familial contradictions to seek out stem cell treatments. For them, the bioethical framework that could best arise out of state regulations is based on an expectation, where the state not only regulates and funds, but also actively enables treatments for orphan diseases and dignity in treatment. These conversations hinge on the fact that the patients are speaking of their biological material being returned to them, without interventions whereby this material is converted to a marketable product sold back to them.

Indian Patients … and *Their* Bioethics

While there have been some concerns about the media enticing patients to travel internationally for treatments (Petersen et al. 2016; Petersen and Seear 2011), the global media takes a conservative or cautious line regarding stem cell treatments in places like India (FitzPatrick and Griffin 2012). The promissory value and hope of potential treatments have increased the scrutiny on regulatory bodies in Asian countries even as patients travel locally and globally to seek cures (Bharadwaj 2013b; Song 2010). Oftentimes the global bioethical framework application required of Indian stem cell therapy clinics and hospitals imagines the patient as a global middle-class (or upper-middle-class) citizen. However, emerging scholarship is turning the gaze to travel within and between countries in the south for medical treatment (Bochaton 2015; Crush and Chikanda 2015; Kasper in preparation; Ormond and Sulianti forthcoming). This does not mean that the term 'medical tourist' is no longer applicable, but rather a critique of the limited focus on the medical tourist being one from the global north, travelling to the global south. Further, in looking at in vitro fertilisation (IVF) treatment seekers in the Middle East, Marcia Inhorn has debunked the idea of patients undertaking expensive travel to partake in very painful (both physical and emotional) procedures as "tourism" (Connell 2015; Inhorn 2015). Getting dental caps installed in India or China, as opposed to the USA or UK, while getting to enjoy a bit of the local cuisine after the treatment, could be dubbed medical tourism. But the invasive procedures Inhorn describes as the standard for assisted reproduction, or the extensive and long-term stem cell therapies witnessed as part of this project, make evident that there is little time, money, or emotional energy to indulge in 'tourism'. In our project, the focus has been on looking at Indian populations seeking out stem cell therapies in Indian hospitals and clinics. While there has been some level of travel involved for a large number of patients, they are not tourists in the sense imagined by some scholarship on medical travel.[8] Rather, they are in spaces that they would not have travelled to had it not been for the diseases or diagnosis. Most of the time, the financial and emotional burden is too immense to allow accompanying family members the chance to be a tourist.

This chapter, while focusing on the larger argument for bioethics that emerge out of the everyday, is premised on the idea that the everyday in stem cell clinics in India is for Indian patients that have few or no options for care and treatment for rare and orphaned diseases.

Keeping this in mind, this chapter draws on our interviews and meetings with patients that were rural or urban middle- and lower-middle-class families with limited resources, but with a determination to live and have a functionally improved quality of life. Frequently, the patient (including adult patients) travelled with both parents and sometimes a relative who was well versed in local transportation systems. Always, one family member was assigned to work with the medical system and to discuss the patient and the treatment. Most of the interviews then became conversations about ethics and regulations, not just with the patient but with familial interlocutors, who offered the most critical take on the treatment and the processes, offering a glimpse into the tensions families resolve internally.

This internal conflict became evident in a few key interviews. In mid-2015, the first author interviewed Ashok Umeshwar, a 61-year-old male with Hereditary Motor and Sensory Neuropathy (HMSN), and his brother. Ashok's brother, Alok, was an MBBS doctor and retired chief medical officer of a district in Uttar Pradesh. Alok was sceptical of stem cell research. Even though both brothers lived in urban and semi-urban spaces, were educated, and had maintained government jobs throughout their lives, they were not part of the upper-middle-class elite. Their financial situation was precarious, and they had asked the hospital to consider their case on a 'special basis' where they were permitted to pay a subsidised price. When pushed on the issue of his scepticism, Alok explained that his understanding of stem cells was that they were most effective and efficient for 'young injuries and patients'. Ashok had been first diagnosed in 1991; the interview took place in 2015. The brothers explained they had a younger brother with a similar diagnosis to Ashok who had passed away; however, he had also suffered from scoliosis. Appleton asked Alok about his doubts.

> Not doubt. I've seen some cases… I've not seen with my own eyes, but I heard about it. There are so many people who want to see with their own eyes, who want to experience it themselves also, so I have no doubt, but

> I have no choice. There is difference between doubt and choice. There is no choice. If there is no treatment, you have to do… to go for a better option. People are saying, people are doing.… this institute, is also a research institute.
>
> (trans. Hindi and English, July 2015)

Alok highlighted the reality that, within medical spaces in India, there was no room for a 61-year-old man suffering from HMSN. There was an implicit understanding that the healthcare systems were overburdened at both private and public levels. While sceptical about this late-stage treatment option, he supported his brother's decision, stating that he believed that stem cell therapy would have been promising had it been given at an earlier stage of the prognosis. While untangling 'choice' and 'doubt', Alok, realised that he occupied a precarious position. At one point in the interview, he turned to the first author and said, 'You've been to many stem cell centres. You know this. The earlier the stage and younger the age, the more stem cells are produced. And as you get older, less cells are produced'. He went onto to talk about his brother being older and the late-stage therapy. He attempted to resolve this internal tension throughout the interview. It was evident that, for Alok, if the therapies were to work it would be easy for him to believe in them despite his doubts. However, if the therapies were unsuccessful, then he would draw on his idea about the late-stage treatment to justify the failure.

Ashok, even in the face of his brother's scepticism, chose to undergo this therapy option. He came to stem cells therapies as a treatment option precisely because of the lack of other viable options. His decision highlighted the fact that patients want to explore all treatment options to live productive, dignified lives regardless of their age. Academic and non-academic debates and critiques must ask whether limited resources at both familial and state levels should be employed to extend the lives of patients in the hope of a potential cure or to improve their quality of life.[9] Fay Ginsburg and Rayna Rapp (2013) have written extensively about the tensions between supporting quality of life for people with disabilities, while also acknowledging that the focus on 'cure' suggests

that a life with disabilities is not liveable with dignity. Their scholarship offers a two-pronged approach to articulating bioethics vis-à-vis stem cells in India's medical reality—to aim to improve the basic healthcare structure for patients with all diseases, while being able to look at stem cell therapies moving in the right direction towards improving treatments for orphaned diseases. When talking about bioethics in India that ought to emerge out of an everyday reality, scholarship needs to be aware of the various tensions (internal, familial, economic, and medical) that patients overcome to seek treatments. While a global bioethical framework would be non-exploitative and a safeguard in some ways, it would not address the limited medical world within which some patients seek treatments or the many barriers they overcome for these therapies.

When asked about the ethics and regulations the state was trying to enact, Alok noted that 'the government has a role in everything. It should be in everything. Currently, in the basic health area, they can't seem to do it properly. So how will it happen here? One option would be for it to be fully supported'. His expectation, like many of the other respondents, was for the state to support stem cell therapies for patients, rather than creating regulatory frameworks that undercut therapeutic support until it becomes a treatment modality offered only through a pharmaceutical product. The expectation of a more involved and responsive state was a theme that emerged in every interview.

Another patient's family, interviewed in Mumbai in November 2014, made evident a similar dynamic. A 48-year-old male patient, Mahesh Tilak, suffered from a spinal cord and brain injury after a motorcycle accident, in a small town close to Goa. After his accident, the doctors feared for his memory, his speech, and his ability to walk. He spent 14 days in the Intensive Care Unit (ICU) facility in a private hospital in Goa. A year after the accident, he was able to speak clearly and was able to retain all of his memory. However, could not use his hands or legs. When interviewed in 2014, he signed the consent form presented before the interview and said, 'this is the first time I have been able to write in a year'. In conversation with Manesh, his intense desire to be able to write, walk, and use his limbs for daily living was evident.

When asked about ethics, regulations, and the role of the government, Manesh and his family offered the view that this therapy should be available even in government hospitals. They acknowledged that the price was prohibitive for some people, but if the public hospitals provided these options, then *garib log* (poor people) would also be able to benefit from the science. While used to not being part of the public health care system for this injury, because of the severity of the injury and treatments thereafter, Mahesh and his family believed that stem cell therapies needed to be expanded rather than curtailed as they could help people in similarly dire situations. In all interviews, it became evident that stem cell therapies ought not to be the first line of treatment; however, for severe injuries and conditions, it should be encouraged by the state within the public healthcare system.

Another patient, Ravinder Sethia, who we met in Gurgoan (a suburb of Delhi), was the parent of a 13-year-old patient suffering from DMD. Ravinder was articulate about the role of the state and what the absence of regulation in the current milieu enabled. He also was wary of the kind of regulations that would need to be put into place to meet particular ethical standards. An upper-middle-class, highly educated, and influentially placed parent, he might be considered a patient advocate as he pushed for therapeutic options for his son. Patient advocates, Thompson points out, are heavily invested in particular treatment modalities (Thompson 2013: 42–43). Mr. Sethia took a sabbatical from his financial advisor position, which required him to travel and live overseas in the Middle East for long durations. He became his son's primary caregiver and devoted himself to finding a treatment for his son's diagnosis. Based on the research studies on stem cell therapies he reviewed, he asked a research lab in India whether they would create a particular protocol based on a successful one he had followed through academic publications. Under medical supervision, this protocol was created and administered to his son at a leading private hospital in India. The location of his son's primary care was not a stem cell clinic or hospital (that is, it did not exclusively work with stem cell therapies) but a regular hospital.

Mr. Sethia used his personal financial resources and proactively negotiated with medical institutes in order to undertake stem cell therapy for

his son. When I asked him about the ethics of stem cell treatments in India and the role of the state, he quipped:

> It is the lack of regulations in India that allow me to try these treatments for my son, or I would just have to sit and wait for the end. If the regulations were very stringent, I would just have to passively sit and wait to see what happens globally and then hope someday some company would decide to bring the treatment option to India. As you know, with DMD, that is not an option.

He continued, in a more sober tone:

> It would be wonderful if the government[10] would invest and develop stem cell therapies in India. But they won't, they can't. It is a very big country with a lot of issues. They will now start to focus on how to shut us down, people like us doing it on our own, rather than help us.

This sentiment was often repeated. The patients and patient-support groups Appleton interviewed were hoping for the best from stem cell treatments. However, they were aware of the precarious space they occupied: if the treatment worked, or even helped marginally, access could be denied based on the guidelines becoming regulations.

The Indian state is currently trying to be responsive to ethical concerns about patient exploitation in some stem cell clinics, but at the expense of other conversations where patients ask for stem cell therapies and treatment, rather than cures, for rare and orphaned diseases. In this situation, the state should be wary of creating a regulatory environment where the only form of permissible biomedical interventions comes from large medical investors in stem cells at the cost of patient care and dignity. A move that would make these treatments virtually unaffordable for the vast segment of people who currently seek them.

The Indian state is not a monolithic entity, but rather a complex assemblage of techno-bureaucratic peoples and policies, particularly when it comes to the ethics and regulations of stem cell treatments. When writing about the Indian state, Akhil Gupta (2012) shows the complexities involved in enabling programmes which aim to help the

poor in India but which fail to do so, leading to a form of structural violence encoded within bureaucratic processes (Gupta 2012). The Indian state and medical establishment walk a fine line, and this moment of bioethical ambiguity should encourage critical voices ensuring a bioethical future that does not merely replicate global frameworks but creates one cognisant of Indian medical realities. The push in India to create systems that replicate the bioethical reality that prevails in the USA and the UK should keep in mind that a bioethical framework meeting global standards means little to a local patient. Particularly, if these standards do not allow patients to survive or seek treatments by using their own material for therapy and receive dignity in their treatment.

Conclusion

The world of biomedicine and bio-innovation is now interconnected in more complex ways than previously imagined. From the first studies of globalisation to contemporary anxieties about the free movement of jobs and people, medicine and technological innovation has been on a forward move to connect, grow, and compete. Stem cell research and therapies are but one example of both academic and practical biomedical global connectivity. This requires a social-scientific perspective of stem cell research and therapy more nuanced than one which situates stem cell therapies 'over there' as problematic. To read scholarship that demonises all stem cell clinics and facilities in India is unhelpful, and does a great disservice to scientific achievements in the field made against formidable odds. This does not mean there should be no scrutiny of bioethics and bioethical applicability in India or other non-Western places; rather, it should be focused on imagining a bioethical response based on those commonalities that help us imagine a better future for patients with diagnoses that do not allow for easy medical diagnosis, therapy, treatment, and care.

This chapter, while a critique of the bioethics enterprise and the anxiety around its bureaucratic reach into already bureaucratic Indian medical governance structures, is not an attempt to undercut the deep need and desire of the patients and researchers involved in this project for a rigorous ethical framework that that would ensure dignity, care, right

to health, treatment, and recovery for patients in India. As the 'embryo panics' around hESC begin to subside, we need increased vigilance for the different kinds of emerging stem cell therapeutics. This vigilance will have to be situated in the reality it wishes to tackle. The established critique from within Euro-American science focuses on the future-facing promise of stem cells and what they can and cannot do when cultured and nurtured in the lab. The focus should be on opening the debate where biomedical systems and new emerging biotechnologies merge.

The most at-risk patients are the local, marginally educated, and those desperate for treatments. One way to ensure an ethical and moral safety net for them is not to ask that the 'regulatory vacuum' in India be addressed immediately to meet global standards. Rather, it is important to recognise that the medical world in India is an ethically fraught space, and although some foreign patients will travel there for biotechnological interventions, it is the local patients who desire state regulations that are responsive and responsible to local needs for care and treatments for rare and orphaned diseases. It is in the absence of state support and the basic rights of patient dignity that local patients seek treatments that may be dubbed 'experimental'. It is patients like Ashok, Bukeshwar, Mahesh, and Ravindra's son who need a bioethics that is responsive to them and their needs and not a bioethical framework that deprives them of therapeutic options because it does not meet globally established bioethical standards. The conditions are not ideal, but this long-term extended project has made evident that there is a lot of room for improvement in not only stem cell therapeutic applications, but also medical care in India. In the quest to instrumentally sanitise the field of stem cell therapies in India by asking clinics to meet globally established bioethical standards, we may perhaps miss the chance to create a new biomedical intervention that does not replicate the historically problematic hierarchies within biomedicine.

Notes

1. Pseudonyms are used for names of all respondents in this chapter.
2. Stem cell therapy is a treatment modality being offered to certain patients whereby stem cells (allogeneic [stems cells received from

a donor] or autologous [patients receives stem cells from themselves]) are injected into a patient.

3. Private health care runs parallel to the public health care in India, with high consultation and treatment fees. The public healthcare system in theory aims to serve all Indians across the diseases and diagnosis spectrum; however, in practice it is overburdened, underfunded, grossly mismanaged, and enables a private medical market to exist for the public service medical practitioners—from nurses to surgeons.
4. The research respondents that I met in this particular stem cell facility called it a 'stem cell hospital' because it was bigger than a clinic (which typically is a 1–3 room operation) and only performed stem cell therapies.
5. iPSC–MSCs are mesenchymal stem cells derived from induced pluripotent stem cells. MSCs are stromal cells that can differentiate into different cell types, including bone cells, muscle, cartilage, and fat cells. Simplistically put, MSCs that are derived from those cells that have been induced from adult cells (iPSCs) rather than embryos are labelled iPSC–MSC.
6. When discussing the 'scientific–bureaucratic chain of phases I through IV clinical trials', the authors talk of the process it takes a chemical composition/product to become a regulatory body approved drug (pharmaceutical product) from its initial discovery in the laboratory, to animal and then human trials before being prescribed and sold.
7. The exact contours of experimental remain unspecific, and the notion of experiment is often invoked in journalistic and scholarly accounts alike to mean a range of processes and treatment modalities. For a critical assessment, see Bharadwaj (2014).
8. Because of the scope of this project, we have also worked with international travellers that would seek out journeys to see the Taj Mahal or explore the local sights and sounds. However, it became evident that this is more in response to the everyday strain the treatment process puts on them and the caregivers. While, it is beyond the scope of this chapter, we note that it is perhaps important to distinguish between domestic and international 'medical migrants'. That is, while some foreign stem cell 'tourists' may indeed step out of the hospital to take in the local sights and sounds this is not tourism per se, but rather a deeply human need for distraction, change of context and a coping strategy given the demands placed on their already frail and often times failing bodies.

9. The affective context of the familial dynamic means people are seldom prepared to even contemplate the question of limited resources and whether to allocate them to extend the lives of next of kin. In fact, who and to what extent gets 'marked' for therapeutic intervention and resource allocation is determined by class and gender dynamics in India. It cuts across public private as well as state and domestic distinctions. The scales are vastly different, but not everyone is treated equally. Although this chapter is not a conversation on class or gender, both were evident in the everyday therapeutic terrains in India over the course of our fieldwork.
10. He used the word 'government' rather than state, so even while paraphrasing, a conscious attempt is made to use his language.

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