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Biogovernance beyond the state?: The shaping of stem cell therapy by patient organizations in India

Abstract:
This article focuses on governance processes in India in the context of biomedical innovation, specifically stem cell research and therapy. Based on qualitative fieldwork conducted between 2012 and 2015, I examine the way in which two patient groups are engaging with debates around how experimental stem cell therapy should be regulated given the current lack of legally binding research guidelines. While public engagement through government-sponsored ‘public consultations’ in this area has been relatively limited in India, patient groups are drawing upon collaborations with medical practitioners to gain leverage in promoting biomedical research and the conditions under which patients can access experimental treatments. I argue that such processes can be seen as an alternative form of biomedical governance which responds to the priorities and exigencies of Indian patients, contrasting with the current measures taken by the Indian state which, instead, are primarily directed at the global scientific and corporate world.

Text:
Commenting on recent moves to restrict stem cell therapy exclusively to clinical trials by the Indian Council for Medical Research, an editorial in the national daily newspaper The Hindu (Regulating Stem Cell Therapy 2014) praised these new measures:
Though belated, the decision to call all the untested “therapies” offered to gullible people as clinical trials is indeed commendable. This would end the rampant exploitation of patients by some doctors. Many untested and unproven stem cell treatments are being offered as a magic bullet for many types of diseases and conditions. Similarly, several untested techniques to separate, grow and expand specific stem cells are available in the country. Besides failing to produce the promised benefits, there is a real possibility of causing greater harm to patients when stem cells are manipulated in the laboratory.

The above excerpt points to the intense debate currently taking place in India over how to regulate and oversee new medical technologies such as experimental stem therapy. Over the last several years, the Indian government has come out with successively more stringent guidelines under pressure from both within the country as well as from the international scientific and medical community to place checks on the number of clinics and hospitals currently offering commercial stem cell therapy to patients from abroad as well as within India. The 2013 Guidelines for Stem Cell Research mark the most recent, as well as most stringent, set of ethical and scientific regulations for stem cell science and therapy. While previous versions of the guidelines (in particular, the 2007 National Guidelines for Stem Cell Research and Therapy) allowed for experimental stem cell therapy in restricted cases, subsequent iterations have sought to limit access to such therapies exclusively to the context of formal clinical trials. In the past, criticism has come predominantly from Western scientists and regulators, although the quotation above suggests that there is growing pressure from within India to enact greater regulation.
The concern with stem cell tourism, particularly within the context of the crossing of national borders by patients to avail themselves of therapies that are illegal or unavailable in their own countries, and the potential for exploitation by unethical providers has become a much-debated topic amongst scientific experts, medical practitioners, regulatory officials and the wider public. In particular, such debates have focused on the rising “stem cell tourism” industry in countries such as India, China and Russia (Salter, Zhou, and Dutta n.d.) and anxieties around the lack of regulation, or uneven regulation, in such contexts. Global bodies of experts such as the International Society for Stem Cell Research (ISSCR 2008) explicitly warn the public against the health dangers of therapies that are offered on a paying basis to patients that are not part of a clinical trial.

While significant media and academic attention has focused in particular on transnational stem cell tourism (Murdoch and Scott 2010; Petersen, Seear, and Munsie 2013; Song 2010) to countries such as India, China and Russia, less is known about the conditions in which patients within these countries access these therapies. Within the context of India, studies by Bharadwaj (2013, 2014), Bharadwaj and Glasner (2009), Sleeboom-Faulkner and Patra (2011; 2009) and Prasad (2015) have documented the complex ways in which Indian patients experience and engage with experimental stem cell therapies given the nebulous regulatory context. Reliable statistics regarding the current stem cell therapy market in India remain scarce but Salter, Zhou and Datta (n.d.:3) estimate the number of providers to around forty and the number of patients seeking stem cell therapy at around ten thousand, making India second only to China in the global stem cell therapy market. While no further
information exists about what proportion of medical tourists from abroad, my own research suggests that while some of the better known clinics attract many of their patients from outside of India, the majority are in fact from within the country. Similarly to their foreign counterparts, Indian patients procuring stem cell therapies face challenges around identifying reliable scientific and medical guidance, the promise for a potential “miracle” cure and the expenditure of significant financial and emotional resources. Of particular concern are the exorbitant amounts of money charged for experimental stem cell therapy: given the legal liminality of current medical treatments in this area, the precise figures around the cost of treatment are generally only known to doctors and patients. Yet, according to some reports as well as my own research, there is evidence that courses of treatment can in some cases range in the US$10,000s.¹

Given the lack of wider state regulation of the stem cell sector in India and the significant risk of exploitation faced by patients, many patient organizations in the country focusing on terminal conditions are increasingly addressing these issues as an important aspect of their work. In this article, I examine the ways in which patient organizations are seeking to condition access to experimental treatments such as stem cell therapy by drawing upon two distinct cases: the Muscular Dystrophy Patients Association (MDPA) and the Spinal Cord Consumer Group (SCCG).² Both organizations focus on terminal conditions for which stem cell therapy is still unproven but having the potential for providing a cure but, likewise, are wary of the significant financial and emotional exploitation that many patients face in procuring these experimental treatments. Despite such similarities, these two groups differ considerably on how each positions itself vis-à-vis the provision of commercial stem
cell therapy for its member patients. While the Muscular Dystrophy Patients Association engages in partnerships with commercial stem cell providers to supply paying “research subjects” to private stem cell companies in return for (what it believes to be) affordable and safe treatment for its member patients, the Spinal Cord Consumer Group draws upon medical networks to influence government agencies to implement current guidelines on stem cell therapy more strictly.

Through an analysis of the way in which these organisations seek to regulate access to experimental medical technologies as non-state actors, and more broadly the discrepancy between the content of state regulatory guidelines and the lack of enforcement mechanisms for stem cell research and therapy, I address wider debates about the state and governance in India (Fuller and Bénéï 2001; Corbridge et al. 2008; Sharma and Gupta 2006). Existing social science scholarship on the state in India has described such processes as evidence of a “soft state” inherent in many Asian countries (Myrdal 1967:1121) which is characterised by a general lack of “social discipline,” a reluctance to obey public laws and rules and corruption. This article, however, focuses less on documenting the lack of state medical regulation in practice, and instead seeks to examine the way in which non-state actors such as patient organisations seek to enact alternative means of biomedical governance. Following on Harriss-White (2003) who examines the social regulation of the informal economy in India, I argue for the importance of understanding medical regulation beyond formal legislation to encompass the informal networks and practices that shape access to stem cell therapy in India.
Through a focus on the work of these two groups and, in particular, the collaborations forged by each with private medical providers, I build upon the idea of “bionetworking” conceived by Sleeboom-Faulkner and Patra (2011) in conceptualising the role of informal networks in wider processes of knowledge production in the life sciences. Specifically, I argue that patient organizations in India such as the ones described here have very little say in impacting processes of biomedical governance when working through normative legal and policy channels to influence state policy.iii Unlike the cases documented by Epstein (1995) and Rabeharisoa (2003) in which patient activists have successfully gained recognition as credible participants in the construction of scientific knowledge, the patient organizations described here must draw upon significantly different strategies to effect change. I argue that it is in their role, firstly, as consumers of specialised health services and, secondly, their status as potential research subjects that these groups are able to command authority in impacting the way in which wider biogovernance is taking place within India.iv

Methodology:
This article is based on fieldwork conducted in India over ten months in 2012-15 seeking to track the “bionetworks” (Sleeboom-Faulkner and Patra 2011) through which innovation in the life sciences, specifically in the field of stem cell research and therapy, and the production and commercialisation of scientific knowledge, takes place. The research consisted of semi-structured and informal interviews with a total of 60 respondents including stem cell scientists, policymakers, commercial stem cell therapy providers and patient group representatives, primarily based in biotech hubs.
such as Bangalore and Mumbai but also in other cities with a patient, policy or commercial presence such as Delhi, Chennai and Ahmedabad. Out of these 60 respondents, 11 were stem cell scientists in government or private research institutes, 17 were scientists or clinicians working in for-profit clinics or hospitals carrying out stem cell therapy on either a commercial or clinical research basis, 6 were managers or marketing representatives for biotech companies or clinics conducting stem cell therapy on a commercial or clinical research basis or stem cell banking companies, 3 were policymakers involved in the regulation of stem cell research and therapy in India, 14 were patient organization representatives or individuals who had personally undergone stem cell therapy. The remaining 9 include individuals outside of these broader “stakeholder” groups but who have important insight on the practice or governance of stem cell research and therapy in India (for example, academics, gynecologists, health NGO representatives, journalists reporting on science and technology issues, etc.). The fieldwork with the MDPA and the SCCG consisted of multiple meetings and ongoing correspondence between 2012 and 2015 with members of the respective groups as well interviews and visits with clinicians, scientists and rehabilitation staff at affiliated organizations. The majority of interviews took place within the offices or professional settings of the respondents, such as laboratories, clinics, hospitals and offices. The exception to this was interviews with patients and patient representatives when, because of mobility issues, I would meet with them in their private residences. In addition to interviews, a core aspect of the study included analysis of documentation such as internet sites, policy briefings, current versions of legislation, industry reports and newspaper articles and adverts were reviewed in order to get a broader perspective of current trends in the area of regenerative medicine in India.
In this article, I draw on the term “patient organization” to refer to a broad spectrum of disease-specific charitable or voluntary organizations, networks and interest groups. Unlike more mainstream public health activists, these groups usually focus on a single condition and are made up and/or led by individuals living with that condition or a family member or caretaker of someone with the condition. Here, I highlight two specific organizations to demonstrate the different ways in which groups are engaging with stem cell therapy governance in India. It is important to note that my argument in this article focuses on patient activists rather than a broader spectrum of people in India living with terminal and/or degenerative conditions who have sought out or considered stem cell therapy as a possible therapeutic option. There is, of course, considerable overlap between the two given that these same patient activists are also, in the case of the SCCG, individuals living with spinal cord injury and, in the case of the MDPA (as well as other muscular dystrophy “parent” organizations), parents of boys with muscular dystrophy or boys who had died from complications associated with the condition. The focus on patient organization representatives, who are generally used to engaging with outsiders around highly emotional issues, was also motivated by a desire to avoid ethical concerns involved in researching people living with terminal conditions and, in the case of muscular dystrophy, children living with a degenerative disease given the fact that the most common form of the illness primarily affects children and young adults.\textsuperscript{vi}

The main barrier throughout the research remained access. The topic of stem cell therapy and regulation of new medical technologies more generally in India remains highly charged. Given the current ambiguous status of legislation and oversight
(Tiwari and Raman 2014), few commercial stem cell providers were comfortable speaking openly about the services they offered, although there remained a surprisingly variability in the level of information they shared with me about the types of stem cell therapy they provided, where they sourced the stem cells used for treatment, and details on patient recruitment. As a non-Indian researcher, I was often greeted with either suspicion as to the intention of my questions or, alternatively, mistaken for a possible investor and presented with elaborate power point presentations demonstrating the supposed evidence of therapies provided and success stories of past patients. Similarly, policymakers and regulators with whom I spoke were equally reticent in discussing challenges they face in implementing current guidelines. In contrast, former and current patients and patient organizations had little hesitation in citing specific figures charged by different clinics as well as the names of doctors they had consulted (or, in the case of patient organizations, doctors that members of their organization had consulted). In this respect, patient organizations in particular were a good resource for finding out the current status of the Indian stem cell therapy market, as well as the challenges patients face in finding reliable information and negotiating medical and scientific information, options and opinions. Triangulating these different perspectives along with information available online and other forms of documentation provides the basis for the arguments in this article.

II. Background and Context

Since the late 1990s and early 2000s, a number of biotechnology companies and private clinics in India have been set up to cater to the growing market in regenerative medicine, particularly in relation to experimental stem cell therapy and umbilical stem cell cord banking. While a number of publicly-funded scientific institutes in the
country have been conducting research in the area of animal and human stem cells for several decades, the expansion of the market in the commercial application of experimental stem cell therapies and banking is much more recent. The sector is not only rapidly growing, but also includes a wide array of activities and actors, ranging from basic stem cell research in government-funded scientific institutes, corporate-sponsored clinical trials for stem cell products aimed at mass-marketization, to, as one patient organization representative put it, “road-side clinics” with dubious credentials offering stem cell therapy as a miracle cure-all.

In response to growing international pressure for regulation of the stem cell therapy market in India, the Department of Biotechnology (DBT, through the Indian Ministry of Science and Technology) and the Indian Council of Medical Research (ICMR) drew up a set of guidelines in November 2007 for the regulation of research and experimentation involving stem cells. A few years after these initial guidelines were published, the ICMR and the DBT organised a series of “public consultations” in early 2010 in six major Indian cities to gather feedback on the original 2007 guidelines. According to several sources I interviewed, however, the majority of these meetings were poorly attended by patients and the general public. Moreover, within the sub-committees set up by the ICMR to provide input on the design and content of the revised guidelines, neither patients nor patient groups were included.

The revision of the guidelines issued in March 2012 (and published in 2013) included new provisions around umbilical cord banking and induced pluripotent stem cells as well as, notably, the omission of “stem cell therapy” from the title of the guidelines. Despite the increased stringency in these later versions of the guidelines restricting
stem cell therapy to formal clinical trials, their status remains highly ambiguous since there is little sense about when (or whether) these will be passed into law, or the mechanisms through which these directives are to be enforced. In practice, the current system can be described as “soft regulation” where the onus for regulation remains the responsibility of individual hospitals and biotech companies (described to me by one of the people tasked in coordinating the guidelines as “self regulation”). To date, there remains a clear mismatch between the hard rhetoric echoed in the regulatory documents prohibiting any stem cell therapy provision, outside the confines of either formal clinical trials or hematopoietic stem cell transplantation which has been in use for several decades.viii

Close ties between the government and industry also lead to blurred boundaries in delineating what constitutes acceptable practice. For example, a report co-sponsored by Yes Bank and the Federation of Asian Biotech Associations (2012) and released by former Indian President Dr Abdul Kalam during a high-level conference held at the elite Indian Business School in Hyderabad was issued in the very month as the revised ICMR guidelines omitting the word “therapy” from the title (March 2012). It stated that “Stem cell therapy is classified as experimental, but adult stem therapy is permissible. Further, ICMR allows the use of embryonic stem cells if the condition or disorder is considered incurable” (FABA 2012, 10). Such statements reflect a clear tension faced by regulators between, on international bodies such as the ISSCR to closely monitor commercial stem cell providers operating in India and, on the other, wider pushes from within the country in recent decades to promote corporate interests, including the biotech sector as well as the stem cell market industry.
In practice, despite the stringent wording of the ICMR-DBT guidelines, many clinics offering commercial stem cell therapy in India operate at a relatively open level and are more wary of legal action by individual patients rather than from the government. In the words of one representative of a small clinic in Mumbai providing stem cell therapy for wound healing, diabetic foot ulcers and cosmetic surgery (breast or buttock augmentation) whom I interviewed:

> How do we say ‘don’t go in for implants and use this’ so we have to have proper PR going on and create some stories in the media that these kinds of treatments are available at this place and people should go and take advantage of this…so, a very cautious approach because we don’t want to end up engaging with someone in the courts and paying them settlements and all these things.\(^{ix}\)

As described here, many clinics and hospitals also use print media to attract new patients, particularly through tie-ups with local papers who write stories about individuals who have sought stem cell treatment at a particular clinic with successful results. For example, the Mumbai Mirror routinely carries articles with headlines such as “Stem cell therapy could help lion attack victim walk again” (2013) and “More than data, I had faith in my body’s power to renew” (2011) which tell the success stories of stem cell treatment found in specific Mumbai-based clinics and hospitals. In addition, the Internet serves as an important means to advertise the range of diseases and conditions that, they claim, can be treated through the experimental stem cell therapies. In addition to including “basic information” about stem cells and regenerative medicine, such sites often include before- and after- photographs and
video testimonials from previous patients attesting to the level of care and the success of the treatments. Patient recruitment takes place through “referrals” from other medical providers and “word-of-mouth” recommendations from other patients. Many providers of both stem cell therapy as well as cord blood banking have extensive networks with other medical practitioners, particularly GPs or specialists, who will recommend them to patients. In the case of the rapidly growing business of umbilical cord banking, many of the larger companies have tie-ups with gynaecologists whereby a commission (usually monetary but sometimes in material goods such as televisions) is paid out for every referral. In addition, most stem cell banking companies have formal tie-ups with hospitals for access to expecting mothers and provide the hospitals with informational leaflets about their services and conduct ante-natal and Lamaze sessions as a means of sharing information regarding the benefits of umbilical cord banking.\textsuperscript{x}

Despite recent moves by the Advertising Standards Council of India and the National Apex Committee on Stem Cell Research and Therapy (NAC-SCST) to clamp down on “false advertising” by stem cell therapy providers and umbilical cord banking companies (Campaign India, February 12 2015), no further steps to discourage such practices have been taken. As such, patients contemplating stem cell therapy face significant obstacles navigating the advice of commercial medical providers with information available on the Internet and through patient support online groups. As I show in the following sections, however, some patient organizations in India are taking an active role in shaping the conditions under which patients are able to access stem cell therapy but, rather than seeking to exert influence through direct advocacy with government officials for greater enforcement on regulation, seek instead to
impact these processes by building relationships with medical providers and scientists.

III. An introduction to patient organizations in India

While there exists an active and longstanding civil society network focusing on addressing current gaps in public health in India, patient organizations focusing on a specific disease as such remain a less overt presence with the exception of a handful of groups focused on HIV-AIDS, cancer, diabetes and cardiovascular disease. This said, since the late 1990s and early 2000s there has been a mushrooming of small disease-specific groups established in India. In general, these groups tend to be small both in terms of the number of staff as well as the range of activities given that, more often than not, they are often self-funded. In the next sections, I focus on two groups: the Muscular Dystrophy Patients’ Association (MDPA) and the Spinal Cord Consumer Group (SCCG) for the Spinal Injury Committee. Both groups seek to provide medical and non-medical support to people living with these conditions and, in both cases, stem cell therapy is of primary concern given the attention it has received as a future cure to currently untreatable conditions

a. Public- and private-interest collaborations to enact stem cell therapy regulation: The work of the Muscular Dystrophy Patient’s Association

The Muscular Dystrophy Patients’ Association (MDPA) is a patient support and parent organization (founded by parents of children with muscular dystrophy) based in the southern Indian state of Tamil Nadu. The organization was founded by Senthil and his wife in 2010 who decided to leave their jobs in an NGO and a government
agency respectively after their son died the previous year at the age of 17 from muscular dystrophy. Because of his own professional background in social activism, Senthil was particularly well-placed in terms of setting up a patient support organization and came to the project with both a personal motivation to support other people in a similar position to himself as well as the professional contacts and expertise to further the cause of muscular dystrophy patients and their families more generally. Since its establishment, Senthil estimates that the organization has registered over 17,000 families across India with members who are living or are carriers with a form of muscular dystrophy. According to him, there remains very little awareness, even within the medical community, about muscular dystrophy which results in patients and their families often spending up to two years before an accurate diagnosis is made.

At the time of the research, the MDPA’s activities were almost exclusively run and funded by the organization’s founders. Senthil and his staff have worked to raise visibility and resources for muscular dystrophy and the organization also conducts several programmes aimed at providing emotional and psychological support to families as well as practical advice for coping with muscular dystrophy on an everyday level and, for poorer families, livelihood assistance. In addition to coordinating standard medical diagnostics and treatments for muscular dystrophy such as genetic testing and physiotherapy, the organization also strongly advocates for stem cell therapy as holding significant potential for an eventual cure and, although it has yet to be formally proven as an effective treatment, recommends it to families as a “support therapy.” In this capacity, the organization acts as a mediator or nodal point between boys living with muscular dystrophy and their parents, on one hand, and
commercial stem cell providers and biotech companies conducting clinical trials in the area, on the other. Given the lack of awareness among families caring for a child with muscular dystrophy about the potential ethical, safety and financial risks involved in stem cell therapy or, at a more basic level, where to find unbiased and trusted sources of expertise and guidance on different treatment options, such collaborations enable the organization to influence how and from whom patients access stem cell therapy.

In addition to the lack of information among patients about treatment options, there is similarly very little awareness around any actions taken by government agencies such as the ICMR to regulate stem cell therapy, or even which agencies are tasked with this function. When I asked him whether patients could go to the ICMR for support in cases of medical malpractice, he responded by stating that “patients don’t even know there is such a thing as ICMR, they’re just looking for an improvement in their health condition.”

Senthil describes one of the main activities of the MDPA as compiling information on different medical providers, in particular those providing stem cell therapy, gathered through past experiences of the organization’s members so that then he will be able to advise others seeking treatment:

Believe me, people are charging...about Rs. 5-7 lakh\textsuperscript{xiv} for every session of stem cell therapy and recommending at least 6-8 sessions! Imagine the amount of money they are charging from a patient! At the Delhi Stem Cell conference last year I met a few families that are literally crying after spending Rs. 17.5
lakh with Dr. G and nothing ever happened [i.e., there were no improvements in condition after spending so much money]…How many documents or names do you want? You name a doctor and I’ll give you documents [i.e., showing that they are charging lots of money for stem cell treatment]. Because as an organization someone will come and tell me ‘I was cheated by a doctor in Mumbai’ so then we have a responsibility to collect all the relevant information because tomorrow when a patient asked me whether he should go for treatment with this doctor I should be able to comment. So for that particular purpose we started writing to different people, as being referred by patients, as a parent organization and started collecting information. I have doctors who have written to me on my personal e-mail saying this is what I charge—80 percent you have to deposit into the account 21 days in advance.

The MDPA now has compiled a wealth of information on a wide spectrum of stem cell providers and other medical practitioners offering treatment for muscular dystrophy—from huge private hospitals affiliated with multi-sector corporations to smaller enterprises comprising only a handful of scientists and medics. In addition, the organization’s files include information the different treatments offered for muscular dystrophy, the fees charged for treatment as well as the experience of others who have visited these same stem cell practitioners.

Given the position of trust that the organization holds with such a large pool of potential patients, the MDPA is often approached by both Indian and foreign companies interested in setting up collaborations. For example, Senthil mentioned that he had recently been contacted by two US-based companies who were interested in
setting up formal clinical trials in India using allogeneic\textsuperscript{xv} stem cell therapy for patients with muscular dystrophy:

[These companies] are willing to launch a formal clinical trial and they are very confident in the results. They have already tested on patients in India without any formal thing. So they want to do it now with a parent organization\textsuperscript{xvi} which will make it legitimate. So for that purpose they need us. They say that the patent right will be shared between these two institutions. Once it becomes a proven result, [they say] we’ll go for a patent and that can be shared under the name of MDPA.

In addition, the organization is also regularly approached by pharmaceutical companies (or individuals working on their behalf whom Senthil refers to as “broker”) interested in obtaining biomaterials from individuals living with MD such as genetic data or blood samples. To date, the organization claims to have refused to hand over such information based on moral and ethical grounds that such “exchanges” are not in the best interests of its members. Senthil speaks about such offers with openness and, while the MDPA has not accepted any such offers, it is clear that access to such biomaterials and bio data is a significant resource both in India and on the global market. Nevertheless, the fact that MDPA is at least perceived by such companies as having easy access to both research subjects as well as biomaterials and data more generally also points to ways in which patient organizations might be able to exploit their access to patients, especially given the lack of wider state regulation in India combined with the global demand for such material.
In its collaborations with stem cell providers, the MDPA reserves the right to have
direct input into the research protocols used by scientists and clinicians in how
treatment is administered (for example, the type and provenance of stem cells used,
dosage, etc.). While Senthil concedes that he does not have formal scientific or
medical training, he relies on his own medical contacts in evaluating the safety and
efficacy standards procedures. Previously, MDPA had collaborated with another
hospital to provide stem cell therapy for its members at low cost. However, the
company decided after one year to change their protocol and begin administering the
stem cells to the patients through an IV. After conducting some research on the use of
IV for stem cell therapy, Senthil and his colleagues discovered that the real reason for
this change was due to the fact that the hospital where the treatment had been taking
place was raising its fees. This price increase caused the commercial stem cell
company with which MDPA has been partnering to choose a different hospital in
which to conduct the stem cell therapy which charged lower fees but which, however,
did not have the facilities to administer the earlier protocol. The change in research
protocol (administering stem cells through an IV) in the end had little to do with
scientific or medical motivations, but rather with purely financial calculations.

When I first began research with MDPA, the organization’s collaborator was a
biotech company in Bangalore, the Stem Cell Biotech Company (SCBC) which, as
part of the agreement, agreed to charge patients a fixed rate of Rs. 3,000 per session
of stem cell therapy, significantly less than the standard rate charged by other
commercial stem cell providers. Unlike the MDPA, the SCBC is a for-profit venture
set up in 2011 which seeks to develop commercially viable stem cell treatments for
muscular dystrophy as well as other conditions such as osteoarthritis, chronic kidney
disease and chronic liver disease. In addition, it has also developing a cord blood
banking service which, according to the company administrator, is a means of funding
the research activities that it is currently conducting. It is headed by Dr Manish who
previously worked as a scientist in Japan and the US and, in collaboration with a
French scientist, has developed a stem cell-based product for curing diabetic foot
ulcers. From my conversations with both Dr Manish as well as other members of the
company, the SCBC is similar to many of the smaller stem cell provider companies
that are cropping up throughout India which seek to draw on expertise that NRI
scientists have gained working abroad and now wish to develop into commercial
ventures given the recent rise of India in the biotech sector.

Partnerships such as that between MDPA and the SCBC represent mutually beneficial
collaborations. On one hand, SCBC was guaranteed a steady stream of patients paying
nominal fess for “support therapy” using stem cells which enables it to turn a modest
profit while developing research that might one day be patentable and have the
potential to become a commercially-viable stem cell product. Similarly, MDPA is
able to guarantee affordable stem cell treatments to its member patients and the
adherence of basic standards of safety and scientific rigour in the treatments they
receive. Ultimately, both Senthil and Dr Manish are entrepreneurial actors in what has
become an extremely high-stakes enterprise, both for patients seeking cures for
terminal conditions as well as the scientists and medical practitioners seeking to cash
in on the “business of biotech.”

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As I shall show in the next section, however, other patient support groups in India are forging very different collaborations with medical practitioners with the intention of putting pressure on the government to implement the current guidelines more strictly.

Patient activism for greater regulation: Spinal cord injury patients in Delhi

Over the past decade, a number of new organizations and platforms have emerged across India aimed at supporting spinal cord injury patients and forging networks between medical practitioners, scientists and physical therapists with an interest or expertise on the condition. The Spinal Cord Association (SCA) is one such group and was founded in Delhi by doctors and other medical and support staff affiliated with one of the premier hospitals in India focusing on spinal injuries, the Indian Spinal Institute (ISI). Since 2006, the SCA has become formally associated with the foremost global umbrella organization for spinal cord patients, the International Spinal Cord Society and aims to promote awareness about spinal injuries both among the general public as well as more specialised professionals working in the area such as clinicians and medical students.

While the SCG is largely led by professional medical staff, a sub-group named the “Spinal Cord Consumers Group” (SCCG) was started in 2010 by spinal cord injury patients affiliated with the ISI to provide patient-led support to other paraplegics and quadriplegics, including those currently treated in the ISI as well as on a broader level throughout the country. The SCCG is part of a wider global network of spinal cord patient organizations under the auspices of the Global Spinal Cord Injury Consumer Network, “an active global network of consumer groups and national/regional organizations of people living with spinal cord injury (SCI).” While it is not clearly
stated why the specific terminology of consumerism is drawn upon in how the network defines itself, a representative of the Indian branch suggested that it was linked with the fact that its members selected the name because of their status as consumers of health services.

One of the founding members of the Indian SCCG is Naresh, a paraplegic who suffered a spinal cord injury in his late 20s after being in an accident. As an active member of the SCCG, Naresh is committed to supporting other patients who have recently been afflicted with a spinal cord injury through a number of different activities ranging from one-on-one emotional support, moderating a list serve which connects patients, doctors, and disability activists across the country, and disseminating lifestyle guidance ranging from topics on fitness and health complications for paraplegics and quadriplegics through accessible documents.

Unlike many other spinal cord injury patients that I spoke with in India, as well as patient support group representatives such as Senthil, Naresh is extremely cautious about the potential of stem cell therapy for offering a cure to spinal cord injury patients such as himself. While many other patients invest immense hope in the stem cell therapy as a means of regaining their previous physical functionality prior to the spinal cord injury, Naresh suggests that it is precisely this “false hope” which makes stem cell therapy so dangerous for other spinal cord injury patients since, on an emotional level, many continue to invest hope in the possibility of a complete recovery. In contrast, Naresh states that he is not interested in receiving stem cell therapy until it has been shown as both safe and effective as any other standard treatment or medicine. Similarly, as he has written to other spinal cord injury patients:
Be aware of the risks before you agree to have an experimental therapy tried out on you…Carefully evaluate if you are ready to risk current stability of life (and spend a considerable amount of money) due to an experimental therapy offering unproven life benefit. Evaluate whether you wish to try an experiment today or wait for a few years till stem-cell therapy becomes as commonplace as, say by-pass surgery (at least).

Naresh’s position on the dangers of stem cell therapy is reflective of the Spinal Cord Consumer Group’s general stance on the issue, namely that stem cell therapy still remains at an experimental stage and should only be embarked upon by patients in the context of formal clinical trials. Other members of the SCCG network with whom I spoke took a slightly more nuanced position around commercial stem cell therapy, arguing that as long as patients were aware of the financial and emotional risks involved, they should have the right to access treatment commercially as long as basic regulatory structured were in place. Yet, the SCCG as an organization takes the position that it is both important to raise awareness of the risks of stem cell therapy, both amongst the general public as well as specifically with other individuals living with spinal cord injuries, and limit access to clinical research. To do this, it works closely with members of the senior management of the ISI who, in their position as leading medics in the field in India have greater sway with government policymakers, to put pressure on agencies responsible for regulating stem cell therapy for stricter implementation of the current guidelines. According to Naresh, these efforts are motivated by the belief of the SCCG and the senior management of the ISI that it is
vital to create a better “governance structure” to regulate the many clinics that are
currently providing different forms of stem cell therapy.

The work of Naresh and the SCCG presents a significant contrast with the previous
case described in this article in terms of the nature of different forms of collaborations
between doctors and patients in the area of stem cell therapy. On one hand, this is
hardly surprising given the significant differences on an institutional level of both the
Spinal Cord Consumer Group and the ISI. While the MDPA collaborates with small
start-up stem cell commercial providers such as the SCTC, the ISI represents the
foremost medical institution in the country working in the area of spinal injuries and
has on-going links with both the Indian government as well as international scientific
and medical community. At the time of my interviews with them, its clinical research
team was in the process of conducting a second clinical trial using stem cells to treat
spinal cord injury and maintains strict adherence to prevailing ethical and medical
standards (Naresh remarked that oftentimes such adherence made patient recruitment
for clinical trials very difficult in that as soon as medical staff would declare that the
treatment was part of a clinical trial, as per the protocols, patients would lose interest).
The ISI thus far has moreover succeeded in financing its clinical research either
internally or through government grants (and thus avoiding seeking funding from
commercial sources) which, according to members of the medical staff with whom I
spoke, was key in ensuring that proper scientific protocols and interests were
observed. In the following section, I show how each of these approaches constitutes a
means through which patients are seeking to condition access to stem cell therapy in
order to safeguard the interests of patients.
Conclusion: Forging local biogovernance through lay-scientific bionetworking in India

This article focuses on the role of patient organizations in India in conditioning access to commercial stem cell therapy in the absence of state-centred enforcement of regulatory guidelines. Writing about stem cell therapy in India, Tiwari and Raman (2014) correctly point out the importance of understanding regulation and governance beyond merely the restricted lens of state intervention through formal codified laws. Rather, the non-statutory nature of current guidelines is not in itself an explanation for the lack of regulation, but a result of wider interactions between different social actors and institutions across different realms including the state, medical profession and civil society. In this article, I argue that despite the lack of implementation of state guidelines, biogovernance does take place, albeit in highly localised and contingent ways. This form of alternative biogovernance can be said to exist “beyond the state” insofar as it entails modes of regulating access to medical technologies through private actors. At the same time, these processes must also be seen as an integral by-product of the wider collusion between the state and for-profit initiatives in the health system in India, a point which has also been documented in the context of “regulatory capture” in the country’s pharmaceutical sector (for example, Srinivasan and Jesani 2012, Jeffery and Santhosh 2009 and Brhlikova et al. 2011).

The two patient organizations described in this article differ significantly on their approach to stem cell therapy, the way in which scientific expertise is channelled and the form of governance advocated. As part of an established network with significant ties to both the international scientific community as well as Indian government
regulatory and funding agencies, the Spinal Cord Consumers Group views stem cell therapy from a position that is very much in line with dominant conventions which hold that biomedical innovation should take place only within the purview of strict ethical and scientific parameters. Accordingly, patients’ interests are best promoted when experimental stem cell therapy should be confined to formal clinical trials (characterised by, for example, treatment that is free of charge for patients, formal regulatory approval, publication of clinical results in peer-reviewed journals and randomised controls). Within the organizational structure of this network, there is a pronounced division between scientific and medical expertise (embodied in the Spinal Cord Society which is largely made up of medically-trained personnel), on one hand, and “lay” expertise of patients such as Naresh who draws on his own experience living with spinal cord injury to support patients in the day-to-day management of the condition. By relying on senior scientists and medics to advocate with government agencies for greater regulation, the organization can be said to defer to (or, from a different perspective, strategically draw upon) dominant hierarchies which attribute greater weight to formalised scientific expertise over the lay expertise of patients such as Naresh.

The Muscular Dystrophy Patient’s Association also recognises that a major problem facing many individuals seeking stem cell therapy is the current lack of state-led regulation of the sector which often leads to the financial and emotional exploitation of patients. In contrast to the Spinal Cord Consumers Group, however, rather than advocating that treatment only be available through formal clinical trials, the MDPA promotes stem cell therapy as a form of “support therapy” which patients can access on a paying basis. This organization also draws upon collaborations with scientists
and medics to implement stronger governance, although in a way that does not rely on
normative state channels but instead by drawing leverage from its access to patients
(both as research subjects as well as paying health “consumers”) to negotiate more
favourable terms with commercial stem cell providers. As such, rather than relying on
state-led regulatory structures to ensure particular scientific and cost standards are
being met, the organization has set up an alternative form of regulation.

The need to resort to such alternative forms of biogovernance by patient groups can
be seen in part as a result of legally binding state guidelines for stem cell research and
therapy. This said, there are numerous cases in which health activists in India have
successfully lobbied for stricter regulation and influenced the design and
implementation of health policy through both the legal system as well as legislative
processes. This can be seen in a range of initiatives, most recently in a campaign
demanding greater regulation of clinical trials which made use of Public Interest
Litigation (PIL) and succeeded in a ruling by the Indian Supreme Court to temporarily
suspend new clinical trials and introduce new government legislation providing
greater protection of research subjects (Terwindt 2014). The role played by public
health activists in working alongside policymakers in the drafting and implementation
of government health programmes such as the National Health Mission is further
testament to the effectiveness of civil society organisations in influencing health
governance by working through normative legal and policy channels to influence state
policy (Unnithan and Heitmeyer 2013; Donegan 2011). Other notable examples
include campaigns for greater regulation of commercial surrogacy (Sarojini, Marwah,
and Shenoi 2011) and ensuring affordability of life-saving medicines despite the
introduction of new patent regimes since India’s inclusion in the World Trade
Organization (WTO) (Ecks 2008).

While groups such as the MDPA and SCCG increasingly draw upon international
models of patient activism in their work and, as such, can be said to be part of wider
global networks, within the context of India they remain marginalised from
mainstream civil society networks whose work is almost exclusively focused on large
public health issues affecting poor Indians. Rare diseases such as spinal cord injury
and muscular dystrophy, while devastating, affect a disproportionately small
percentage of the population and are therefore not seen as a priority for many public
health groups. Similarly, while concerns over regulation of the private health sector
and clinical research have been a priority for health activists in India (for example, in
the case of clinical trials), similar concerns around commercial stem cell therapy
remain peripheral given the fact that only people who have the financial capacity to
pay for expensive therapies are affected (even though, in many cases, these treatments
will incur indebtedness and extreme sacrifice).

Likewise, groups such as the MDPA and the SCCG have also remain marginalised
from state-level decision-making processes around access to commercial stem cell
therapy which remains the domain of scientific and medical experts, as well as the
commercial actors sponsoring biomedical research and treatment. Because of these
factors along with the increasing privatisation of the healthcare system and the lack of
state regulation of the stem cell therapy market, the ability of patients and patient
advocacy groups to exert influence, even on a localised and contingent level, lies not
through their moral or political claims as patient-citizens, but rather through their
leverage as consumers of healthcare and research subjects. This is evident in the very name of the group of spinal cord injury patients (the “Consumer Group”) described earlier in this article. Similarly, the MDPA is able to negotiate for better terms with commercial stem cell providers with whom it collaborates through its ability to supply paying research subjects. The central role of the market both in how health care is distributed as well as in the way in which state regulatory structures are implemented evident here thus needs to be understood through a wider analysis of how claims to citizenship are enacted outside of normative processes of democratic electoral politics but through contingent and often precarious means (Das 2011).

Sleeboom-Faulkner and Patra (2011) have emphasised the importance of looking beyond formal scientific collaborations to understand the way in which non-scientific activities and networks (“bionetworks”) contribute to knowledge production and innovation in the life sciences. In this article, I have argued that the MDPA and the Consumer Committee seek to shape the conditions under which patients access stem cell therapy, not through direct advocacy with state agencies, but through informal lay-scientific networks stem cell scientists and clinicians. Given the absence of broader regulatory enforcement by the state, this can be seen as a form of alternative form of biogovernance through which scientific and medical authority and expertise is not contested but rather channelled in furthering the interests and well being of patients (as conceived by the groups representing them).

Current global efforts at promoting the public interest through uniform standards for bioethics and scientific experimentation in the area of stem cell research and therapy remain largely devised by policymakers in conjunction with elite scientists and
industry and are aimed at striking a balance between encouraging biomedical
innovation and protecting the welfare of patients. Yet, often such efforts at regulation
have neither taken into account the voices of patients, nor have they succeeded in
effectively protecting them from exploitation and malpractice. While health activists
have been successful in influencing health policy in India through more conventional
means of citizen action, patient groups such as the MDPA and the SCCG instead rely
on medical-scientific networks to promote the agenda of their members. However,
they play an important role in advocating for issues that otherwise would be
overlooked, especially given the close collusion of the government with industry and
commercial interests. Without actively involving these voices, such efforts will
ultimately fall short in laying out the conditions for the responsible and responsive
production of scientific knowledge.

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1 A study conducted by the Stem Cell Network of the Health Law Institute in the
University of Alberta around direct-to-consumer marketing of experimental stem cell
therapy by clinics in different countries found that the average price for treatment
came to CAN$21,500, excluding travel and accommodation for patients and their
caretakers (Lau et al. 2008:594). My interviews with patients who had researched or
undergone stem cell therapy suggest that more established stem cell therapy providers
in India can charge similarly high fees, depending on the condition being treated and
the financial capacity of the family and her family. As such, while stem cell treatment
for terminal conditions such as muscular dystrophy and spinal cord injury could cost
around Rs 8 lakhs (USD$12,000), more cosmetic procedures (for example, using
adipose stem cells for breast augmentation) would cost around Rs. 2 lakhs
(USD$3,000).
All names of people and organizations have been anonymized in this article.

Or what is often referred to as “direct citizen action” (khanna et al., 2013)

In this, I use the term “biogovernance” to refer to the regulation of the life sciences and biomedical sector, whether by the state or non-state actors. Within the specific context of stem cell sector, regulatory activities include the ensuring that scientific, ethical and safety standards are adhered to by practitioners and that treatment is administered in a transparent and accountable way.

Media sources included English language national newspapers such as The Hindu, Times of India, Hindustan Times, Indian Express. In addition, regional papers for areas with large biotech sectors and or policy relevance such as Mumbai, Bangalore and Delhi were also included as well as press releases for new industry reports on the stem cell sector and official policy documents (search terms included “stem cell therapy,” “stem cell research,” “India,” “Mumbai,” “Bangalore,” “Chennai,” “regulation,” “Indian Council for Medical Research (ICMR),” “Department of Biotechnology”). Lastly, the specific websites for commercial stem cell providers and biotech companies, research institutes conducting stem cell research, patient organizations and patient list serves (in particularly for conditions in which stem cell therapy is particularly in demand such as muscular dystrophy and spinal cord injury) were also included in the documentation review.

In all cases, informed consent was gained from respondents and the purposes of the research explained in detail.

These were subsequently published in 2007 as the National Guidelines on Stem Cell Research and Therapy.

See ICMR website: http://www.icmr.nic.in/icmrnews/NAC.htm

Interview 09/03/12.
As Patra and Sleeboom-Faulkner (2009) have documented, in some cases individuals posing as patients will approach potential clients considering stem cell therapy in order to recruit them for treatment in a specific clinic.

Interview with Dr P, a gynecologist in a “boutique maternity hospital” in Bangalore (19/11/12) and A, a marketing representative for a large umbilical cord banking company with branches across India (9/10/12).

Muscular dystrophies are a group of inherited genetic conditions which cause the muscles to progressively weaken. One of the most common and severe forms affects boys in early childhood; the average life expectancy in such cases is 27 years.

Approximately US$8000 - $11,000.

Using stem cells from another person.

The term “parent organization” here is used to refer to a patient organization which is comprised predominantly of parents of children living with muscular dystrophy (rather than the patients themselves, who because of the early onset of the condition are children or youths).

More recently, the organization decided to temporarily suspend the collaboration after Dr Manish decided to terminate the research focusing on muscular dystrophy in order to concentrate exclusively on using stem cells for skin grafting purposes. Senthil has in the interim applied for permission from the Indian Council for Medical Research to continue the clinical research and plans to continue working with the stem cell scientist previously working alongside Dr Manish. At the time of the writing, the organization had finally concluded an exhaustive search for an affordable and reliable company from which to source stem cells and had set up a partnership with a local hospital to administer treatment once official permission is granted.
Excerpt from “Stem cell therapy: The cautionary paradigm,” written by Naresh.

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