Experimental stem cell therapy: Biohierarchies and bionetworking in Japan and India

Margaret Sleeboom-Faulkner
Department of Anthropology, University of Sussex

Prasanna Kumar Patra
Department of Anthropology, University of Utkal

Contact author:
Margaret Sleeboom-Faulkner, Department of Anthropology, ARTC 209, University of Sussex, Brighton, UK
E-mail: m.sleeboom-faulkner@sussex.ac.uk

Abstract
This article concerns new developments in autologous adult stem cell research in Japan and India through the notions of biohierarchy and bionetworking. It conceptualizes how human subject research in one country may be turned into experimental stem cell therapies in another through bionetworks. We analyse the processes that enable researchers in Japan to discard a therapy as being of reputational risk, while researchers in India employ it so that it becomes reputation enhancing. At the same time, scientists from both countries collaborate in and potentially benefit from the same bionetwork. Explaining how the recruitment of patients and scientists is organised through bionetworking, this article analyses how experimental research in India thrives using Japanese technologies. The concept of biohierarchy illustrates how inequalities in health and standards of living in India and in Japan underpin the methods by which researchers,

1 The final, definitive version of this paper has been published in Social Studies of Science, volume 41, issue 5, October 2011, pp.696-707, by SAGE Publications Ltd. All rights reserved. © The original article published in Social Studies of Science is available online at: http://sss.sagepub.com/content/41/5
medical professionals, managers and patients collaborate in bionetworks. The concepts of ‘boundary object’ here captures the ways in which the meaning of experimental therapy is embodied by subjective categories projected onto it by patients and scientists alike. The article is based on fieldwork conducted by both authors during three months between September and December 2008 at various locations in India and Japan. Data for this article were collected from a wide range of interviews with stem cell researchers, medical doctors, coordinators, managers and patients, primary and secondary sources gathered at these centres, and through web and archival research.

**Keywords:** stem cell therapy, bionetworking, biohierarchy, Japan, India

**Introduction**

It has been argued that a democratically constituted public sphere, including equitable health service and transparent institutions to facilitate open debate and regulate interests, should be regarded as the third essential foundation of medical research ethics, next to clear-cut rules and good face-to-face relations in biomedical research (Geissler et al., 2008: 696). This article explores how experimental stem cell therapy (ESCT) thrives under the relative absence of this third foundation of medical research ethics in one country, India, and its relative existence in another country, Japan. To this end, the article deploys the concept of bionetworking and coins the concept of biohierarchy, investigating the activities of entrepreneurial research scientists, exemplified by the case of ‘Big Man’.
Especially with large numbers of Indian and Chinese middle class people studying abroad, there has been a significant increase in the number of scientifically skilled, multi-lingual and multi-cultural individuals. Many of these talented people, however, are hard-pressed to pay back financial debts and to publish in high-quality science journals. When in a position to use their skills and status in hospitals and research centres, opportunities arise to pursue collaborations for ambiguous reasons, sometimes to the neglect of the consequences for patients. The hopes and desperation of patients, the ambitions of resource-poor researchers, and the moral ambiguity and needs of scientists are the basic elements of bionetworking in experimental stem cell therapies.

One Japanese scientist, Dr. Umemura, relates how an increasing number of returnees to India and China set up their own companies, or persuade hospitals and universities that their training in prestigious educational centres abroad qualify them as promising heads of laboratories in hospitals and research centres. Dr. Umemura, whose immunology therapy is licensed to Indian clinics, complains of the risk of such ventures to the reputation of the donor of a technology:

There are many Chinese doctors that upon returning to China use the biotherapies in all sorts of cases. It is not certain that they use them properly. In extreme cases, in China they use the technology for their own purposes and act as if it is theirs to make money. This I have seen for myself. (interview, 18 November 2008)

These entrepreneurial scientists, who we call ‘Big Men’ (or Women), borrow authority from their familiarity with the languages, scientific knowledge, political cultures and
science regulation of various communities to set up lucrative networks. Such bionetworks are subjectively based on values that we analyse as and translate in terms of biohierarchies. Big Men are the nodal agents that mediate medical supply and demand between regions, countries and institutions: they make use of the unregulated interstices by skilfully manipulating their networks.

Theoretical conceptualisation: Bionetworking, biohierarchy and Big Man

Bionetworking is a social entrepreneurial network activity involving biomedical research and healthcare organisations that thrive under conditions of health inequality (Patra and Sleeboom-Faulkner, 2009). A bionetwork consists of a plurality of actors engaged in ‘biotechnical ventures’ (Waldby and Mitchell, 2007), working across geographical spaces, regulatory regimes and social institutions. A bionetwork exploits differences and similarities in the provision of healthcare, levels of wealth, standards of scientific development, and research regulatory regimes and their implementation.

Research that involves experimental therapies makes significant use of bionetworking techniques for patient recruitment. Unlike recruitment in clinical trials, where there usually is clarity about the experimental nature of therapies, recruitment via bionetworking makes use of confusions and ambiguities around the research process and care aspects of clinical research (with an emphasis on research) and clinical therapies (the business of care), selling its services as experimental stem cell therapy. Efforts are usually put into keeping clinical research trials as ‘scientific’ as possible, meaning that deviations from ‘standard’ field sites tend to be explained as part of the external aspects of trials (Will, 2007; Geissler et al., 2008: 705). Such external aspects might include
diagnostic cultures, ethnic variability and clinical organisation (Rothwell, 2005). Their incorporation into the planning of trials is thought to make trials more successful scientifically. In contrast, ESCT is predicated on the ambiguity and variability of ‘external’ aspects of trials, because the development of scientific knowledge is not the main aim. Knowledge of similarities and differences among the regulatory conditions, healthcare access, political regimes, and socio-cultural background of various populations is regarded as useful and is exploited in the business of bionetworking.

In other words, while deviating aspects of medical research trials ideally are externalized to improve both the ethical and scientific basis of the research, in bionetworking they are actually manipulated to facilitate the bric-a-brac of research and healthcare management in ESCT practices. While an ideal-typical setting of clinical trials requires a bioethics based on reciprocal, participatory engagement across different worlds of experience (Kleinman, 1995: 67), such engagement in bionetworking is most conducive to the peddling of experimental therapies in the various corners of a transnational network by Big Man entrepreneurs.

The concept of Big Man is well known in anthropological analysis and refers to an individual who is highly influential but has no formal authority in a community. The Big Man maintains his position of power and recognition through persuasion, knowledge and savvy (Sahlins, 1963). In the present case, Big Men make use of what we call bionetworking: personal skills that facilitate small-scale connections that constitute and mediate relations in an international network in ESCT. This might be contrasted with the work of Contract Research Organisations (CROs). CROs link foreign and domestic
interests, mediating between the interests of large pharmaceutical companies, clinical trial centres in hospitals, and government agencies.

Though research has been conducted on offshore outsourcing of large-scale clinical trials (Petryna, 2007; Cooper, 2008; Sunder Rajan, 2006) and on the bioethics of medical tourism and its institutional organisation (Kiatponsan and Sipp, 2008; Wahlberg and Streitfellner [in press]), not much light has been shed on how patient recruitment is organised and combined with human experimentation in ESCT. We present an example of a Big Man entrepreneur turning human subject research in Japan into experimental stem cell therapies in India, and describe how the recruitment of patients and scientists is organised through bionetworking.

We speak of bionetworking because the networking involved requires knowledge of institutions and subjective values related to the health of human life integral to the networking activities. Bionetworking requires knowledge about differences in needs, lacks and situations of patients and scientists in different circumstances and places. Big Men categorize people according to markers of health, wealth, education, employment, level of scientific advancement, national origin, and race. Such markers arrange groups of people in what we call biohierarchies. The concept of biohierarchy here refers to divergent appreciations of life values and human existence in different national, class and health environments (Sunder Rajan, 2007). We use the concept both to explain how Japanese and Indian researchers who work on stem cell therapies are persuaded to risk their reputations by trusting a Big Man well enough to provide him with their technologies, and also how patients are persuaded to part with their money and place their lives in the hands of the Big Man and his company.
In this biohierarchically moulded transnational ‘space of transaction’ (Nowotny et al., 2001: 86), Big Men are ‘boundary persons’ and stem cell therapies are boundary objects. According to Susan Leigh Star and James Griesemer (1989), boundary objects inhabit several communities of practice and satisfy the informational requirements of each of them. They are both plastic enough to adapt to local needs and the constraints imposed by the parties employing them, yet robust enough to maintain a common identity across sites. Stem cell therapies are viewed in one country as being a source of reputational risk to scientists (Larkin, 2003; Sleeboom-Faulkner, 2010), and in another as being a reputation enhancement, while scientists from both countries collaborate in developing ESCT through one and the same bionetwork. ESCT is moulded as an ambiguous abstraction to attract patients and researchers in both Japan and India, sustaining a conversation by people with clashing interests and contrasting points of view (Gieryn, 1983). The performance of the Big Man as a ‘boundary person’ is essential to this conversation. The ease with which the Big Man as an outsider (necessarily) occupies a hybrid insider position in the two countries makes him successful as a boundary person and bionetworker.

Analysis of this success sheds light on the perspectives of parties involved in organising risky scientific quests. This article delineates and analyses the seemingly fractured behaviors and goals of scientists. Japanese scientists appear to positively engage in collaboration with Indian researchers to develop science, conduct clinical research and help patients all at once. Using a case study of a Big Man active in Japan and India, this article explores the circumstances under which scientists come to see only the positive, and not the dubious consequences, both at home and abroad, of their international
collaborations, and Big Man comes to regard himself as helping scientists in Japan, researchers in India, and patients in need to overcome their difficulties. Analyzing the activities of Big Man in this article, we describe the organisational structures of bionetworking, the diverging life-world conditions expressed in the term biohierarchy, and the unifying activity of boundary making that enable the transnational experimental practices of Big Men in general.

To what extent do structural differences and inequalities draw out the talents in Big Man as a matchmaker, a problem solver, an opportunity finder, and a fortune seeker? As will become clear, Big Man is not a cool neoliberal player in the ‘free’ market economy, but a creative builder of a calculative form of bioethics: the discrepancies in value regimes across social, economic, and regulatory boundaries form the solutions to the problems of scientists, researchers and patients, which Big Man aims to solve through culturally embedded planning, reasoning and marketing.

Method and overview

The data on the Big Man case in this article were collected by both authors during three months of fieldwork between September and December 2008 at two leading centres of India’s private sector regenerative medicine initiatives, the X Institute for Regenerative Medicine (XIRM) based in Chennai and the Japanese-Indian joint-venture Z Centre for Regenerative Medicine (ZCRM), as well as various stem cell research centres in Japan, including ZCRM, based in Tokyo, private clinics in Tokyo, the Research Institute for Medical Frontier in Kyoto, and the RIKEN institute and CDB in Kobe. Data for this paper were collected from a wide range of interviews with stem cell researchers, medical
doctors, coordinators, managers and patients, primary and secondary sources gathered at these centres, and through web and archival research. When we first became interested in the activities of a particular Big Man in connection with research on international stem cell science collaborations and research regulatory regimes in Asia, we hypothesised that more than simple market principles of cross-border demand and provision were at play. We decided to look into how the activities of Big Man and ZCRM explicitly relate to regulatory differences, variable healthcare needs, and differences in healthcare provision, availability and opportunity in Japan and India.

We introduced ourselves as interested in how, with the help of Big Man’s transnational activities and the networks he has set up in Japan and India, charity activities in India are financed and organised. The first author visited people and institutions connected with ZCRM in Japan, while the second author did the same in India. To a certain extent, Big Man was helpful accommodating us in his busy schedule. He could not find time to meet with the second author in India, but arranged a meeting with a junior in their rather dilapidated office in Chennai. However, Big Man welcomed the first author in ZCRM’s Tokyo high-rise office, and kindly made various introductions to collaborators. This study also draws on research into stem cell research regulation and ethics in Japan, for which over fifty interviews were conducted with stem cell researchers in the Kansai and Kanto regions.

In the next two sections we describe the setting of stem cell research in India and Japan and Big Man’s bionetwork around ESCT. Following that, we discuss Big Man’s role as a boundary person maintaining and balancing ties with stakeholders with diverging interests in ESCT. The same technology can become an object of material and
ideological negotiation in transactional spaces involving differently equipped systems, symbols of health, reputation and science, and unequal relations of power. We examine the values mobilised by Big Man as a boundary person, which create a hierarchy of health-related human groupings, or what we call a ‘biohierarchy’. In our conclusion we revisit the question of the role of public debate and transparency as a condition for ethical science, and discusses the driving forces behind the bionetworking practices of Big Man and his collaborators.

Setting: Stem cell research in India and Japan

Over the past decade, both India and Japan have placed great emphasis on economic growth through innovation in the life sciences, particularly in connection with stem cell therapies, whose market is expected to grow rapidly in ageing societies and in the growing middle class in the rising nations of India, China and Brazil. Stem cell research in India and Japan is a rapidly growing field and has been expected to yield therapies for a wide range of currently untreatable diseases, such as spinal cord injury, myocardial infarction, Alzheimer’s disease and diabetic ulcer. In India, the government and private industry have invested heavily in research institutes studying stem cells (Sleeboom-Faulkner and Patra, 2008) and the Indian government has initiated stem cell programmes with the aim of promoting both basic and translational research in view of their potentially lucrative applications (Sharma, 2006). Similarly, stem cell research has been a focal point of the life sciences in Japan’s Millennium Project, which aimed to boost
economic development and therapies for its fast aging population (Sleeboom-Faulkner, 2008). Government investments in stem cell research have been substantial, expressed in the establishment of large stem cell hubs at RIKEN institutes (Tsukuba and Kobe), Keio University and Kyoto University.

In the midst of this up-beat policy-making context of innovation, investment, and high expectations, uncertainty reigns over the extent to which research funding will lead to results and experiments can be translated into effective stem cell therapies. Great pressure on scientists to produce international science publications and to enter collaboration with industry to develop effective therapies (Saegusa, 1999) has led to the concern that scientists may be tempted to get involved with dubious forms of human experimentation in both India and Japan. At issue in the case study outlined below is the questionability of the scientific basis, medical efficacy and regulatory permissibility for using adult autologous stem cell therapies, which make use of the patient’s own stem cells, as well as the ambiguity with which adult stem cell therapy is promoted as ESCT in many hospitals and clinics. Although adult autologous stem cell therapy is widely considered to be free from ethical problems and thought to have great therapeutic potential (Khan, 2007), the international scientific literature recommends ESCT only when used in a strictly monitored environment (Partridge, 2003; Strauer and Kornowski, 2003; Passier et al., 2008; Wainwright et al., 2006). Similarly, the International Society for Stem Cell Research (ISSCR) makes a clear distinction between routinely used and experimental stem cell therapies. Bone marrow stem cell therapy is a well-established treatment for blood cancers and other blood disorders. But new clinical applications for stem cells are currently being tested for the treatment of musculoskeletal abnormalities,
cardiac disease, liver disease, autoimmune and metabolic disorders, and other advanced disorders (e.g. ISSCR, 2008). These new therapies have been offered only to a very limited number of patients as a last resort and free of charge.

The uncertain nature of these stem cell therapies led the Indian Council of Medical Research (ICMR) to develop research guidelines to guide the development of new stem cell therapy testing (ICMR, 2007). The ICMR is the official Indian body that formulated the guidelines for stem cell research and therapy. But, as the guidelines are ‘soft’ and not clearly formulated, enterprises regularly ignore them (Patra and Sleeboom-Faulkner, 2009; Salter, 2008, Bharadwaj and Glasner, 2009). Many clinics in India practice on and sell un-vetted stem cell therapies to patients who cannot find alternative treatment methods. The scale of this research is such that the ICMR does not have the capacity to control violations (interview, ex-official ICMR, N. Agarwal, July 2010). At the same time, belief in the progressive image of modern science raises hopes that crucial steps will occur in research fields and therapeutic areas where foreign scientists fear to tread. The advanced aura of Japanese technology, then, is mobilised to attract patients in India.

In Japan, problems of a different nature arise. The development of interim guidelines for somatic stem cell research in a clinical setting were only finalised in July 2006, despite years of preparation and debate among scientists, patient groups and handicapped groups (Japan Ministry of Health, Labour and Welfare, 2006). Guidelines for stem cell research in Japan are also soft, but social control through gate-keeping bureaucrats and self-regulation is strict, and researchers experience the guidelines as limiting, because they require researchers and hospitals to go through lengthy processes.
of application for permission (Slingby et al., 2004). Japanese stem cell researchers are aware of the problems associated with premature clinical applications. Time and again, interviewed stem cell scientists insist that it is not yet clear how stem cells regenerate and repair tissue, how adult stem cells work in different parts of the body, how to standardise the cells, and how to improve the efficacy of the therapy. In one instance, the company J-Tec, which tried to regenerate skin using autologous bone marrow stem cells, had to wait for more than seven years before its trials were recognised (interview J-Tec, 9 November 2008). Other researchers complained about not receiving permission to use mesenchymal stem cells in the mouth (interview Ushi, 22 October 2008). Although these complaints have prompted the Pharmaceuticals and Medical Devices Agency (PMDA) to reorganise application procedures, and the Ministry of Education, Culture, Sports, and Science and Technology to reorganise science research around thematic and geographic regions, bureaucratic challenges are far from resolved (interview, Hara, 7 November 2008).

The challenges to conducting human subject experiments for new therapies in Japan do not just relate to social control, the media and the bureaucracy, they also relate to patient recruitment. Japan, as an affluent welfare society, provides a high level of healthcare for the vast majority of its population, and supports adult stem cell therapies in the case of untreatable and life-threatening diseases. But only when no other drugs and therapies are available do Japanese patients seek refuge in experimental medical trials for which they are not covered by insurance, or do they go abroad to look for available/cheap medical assistance (Fukuda and Nakai, 2008; Yuasa, 2007). In less wealthy countries that lack universal healthcare coverage, such as India, to many patients experimental clinical research may seem the best treatment option (cf. Patra and Sleeboom-Faulkner, 2011).
Researchers who are waiting for approval from regulatory organs in Japan can be tempted to conduct research in countries that have a large supply of patients at the bottom of a biohierarchy (interview, Dr. Egawa, 17 Nov 2008). Regulatory and socio-economic discrepancies, then, have opened up a new transnational space for clinical research, and have become the playing field for what we call bionetworking by Big Men (Patra and Sleeboom-Faulkner, 2009).

**Big Man’s bionetwork**

Dr. Big Man is the Indian founder of the Z Centre for Regenerative Medicine (ZCRM), an Indo-Japan joint venture institute based in Chennai. Big Man is a research manager, scientist, and businessman all in one, and knows how to combine his various functions across borders. Big Man previously worked through Z Bio Sciences Private Limited, established in May 2000 with Japanese equity. He engages in diverse fields of activity: health care; R&D in the life sciences and plant biotech; herbal medicine; technology transfer between Indian and Japanese institutes; and importing and marketing of surgical devices, biotech labware and products for agriculture. Through his work in Chennai, Big Man expanded his links with Japanese researchers, scientists, medical doctors and biotech companies interested in investing in stem cell therapy in different areas: clinical trials, herbal medicine, an selling of medical equipment and chemicals. His career follows life science trends: while in a position at Yamanashi University for over a decade, Big Man became the lead researcher and director of the Chennai laboratory of ZCRM, and Director of the ZCRM in Tokyo (Z International), which was registered in November 2008. ZCRM started as *Standard Private Company Limited* in 2000 with Japanese equity,
after which it became *Nichi-In Drug and Device Private Limited*. Later it became *Nichi-In Bio Private Limited* and, finally, in 2005, it became the *Z Centre for Regenerative Medicine* (ZCRM).

Over time, Big Man has signed many collaborative agreements between research institutes in Japan and India. Those signed with Japanese institutes pertain to science research, while those with Indian institutes pertain mainly to translational research and therapeutic applications. Thus, ZCRM has few (basic) science collaborations with Indian institutes (only the Department of Biotechnology of Acharya Nagarjuna University is mentioned). In Japan, however, Big Man has research collaborations with Waseda University (Department of Polymer Sciences, Tokyo), Mebiol Inc. (Tokyo), the Kawamura Institute of Chemical Research (Yamanashi University-Faculty of Medicine), Yamaguchi University-Faculty of Medicine (Ubu), and the Biotherapy Institute (Tokyo). Big Man’s network, then, displays a rough division of labour between scientific research in Japan and translational research in India.

Big Man opened ZCRM’s Tokyo office, headed by Mr. Yamazaki, on 7 January 2008. The office serves to promote medical tourism in India by tapping into the Japanese market, developing collaborations with Japanese institutes and industry, and dealing with intellectual property related issues in Indo-Japanese research. Big Man claims that ZCRM’s research on stem cells in fields such as ophthalmology, hepatology, orthopedics, dermatology, dentistry, and oncology takes advantage of Japanese advanced technologies. It also boasts several firsts to its credit in clinical studies using stem cells for Spinal Cord Injury (SCI) and Liver Cirrhosis. Furthermore, Big Man claims that ZCRM is the first institute in India to use Autologous Immune Enhancement Therapy
(AI) for cancer, in which the patient’s own Natural Killer cells and T-Lymphocytes are used to curb cancer cells (ZCRM’s website, accessed on 22 January 2009).

Big Man provides stem cell isolation/expansion services to Indian hospitals. Formally, these hospitals work according to the guidelines of the Institutional Ethics Committee and Institutional Committee for Stem Cell Research and Therapy (IEC/IC-SCRT) stipulated by the ICMR. The guidelines permit the use of autologous stem cells in research and treatment, provided the protocols are approved by the IEC and IC-SCRT and registered with the National Accreditation Committee for Stem Cell Research and Therapy (DBT-ICMR, 2007). But, as there is no adequate supervision over IEC/IC-SCRT, and, as pointed out by Big Man, the National Accreditation Committee has not yet been formed, and regulation does not stand in the way of research and therapeutic applications (telephone interview, BM, 17 January 2009). To avoid becoming entangled directly in the ethical issue of applying unauthorised therapies, Big Man uses his collaborative networks to recruit and maintain a pool of patients. ZCRM recruits, treats and charges patients indirectly. According to the coordinator of ZCRM:

The concerned collaborative hospitals recruit patients, treat them and charge them for the services. We do not directly charge the patients. We charge the hospitals for our services. How much we charge, I cannot tell you. Because, you know, as per the ICMR guidelines, it is an experimental therapy and for experimental therapy we should not really charge… We charge for the laboratory expenses. It is very nominal. (Interview, 5 November 2008)
Big Man avoids applying for clinical research authorisation and directly charging patients through bionetworking, illustrating his biomedical ethic.

Big Man did not take the time to meet the second author in India. Instead, he told her to meet the public relations officer, Mr. Kamal, at the down-market office and laboratory at Vijaya Hospital compound in Chennai. This makeshift clinical hut operates in the not quite illegal healthcare interstices where control is either absent or ineffective. Mr. Kamal was quiet and taciturn, and only conceded to share a PowerPoint presentation of ZCRM. Any questions were directly referred to ‘The Director of ZCRM’.

ZCRM’s activities in India, according to Mr. Kamal, cover diverse areas: First, it performs ‘R&D’ at lower costs than its counterparts in Japan and applies for Indian patents for basically unaltered, but now tested, technologies; second, it stores various types of stem cells, and aims with external funding to establish the world’s first corneal endothelial stem cell bank (CESBANK); third, it finds users for Japanese technologies, whose fees they reinvest in the enterprise; fourth, it showcases selected patients to advertise the effectiveness of its experimental therapies, to attract patients and new collaborations for stem cell tourism, both in India and in other parts of Asia, such as Malaysia, Singapore, Indonesia and Brunei, where the Z-Asia Centre for Regenerative Medicine has been set up; fifth, it provides international training programmes via the web and contacts in Canada (with the University of Toronto, McMaster University, and the University of Ottawa) and Asia; and, sixth, it advertises itself as having ‘excellent networking at all levels (local, national and global) in all three areas (basic, translational and clinical studies).
According to the Public Relation Officer of ZCRM in Chennai, ZCRM, with various collaborating centres, has treated more than 150 SCI cases (in 6 hospitals), 25 cardiac disease cases (2 hospitals), numerous peripheral vascular disease cases (2 hospitals), 35 liver cirrhosis cases (2 hospitals), and 2 oral sub mucosal fibrosis cases (2 hospitals). ZCRM competes with other research centres, especially Manipal Institute for Regenerative Medicine (MIRM) in Bangalore. Among ZCRM’s major achievements, the officer claims to have been India’s first to perform immunotherapy for cancer patients; perform stem cell therapy for diabetic ischemia patients; perform stem cell therapy for SCI; have two publications in stem cell therapy and ten clinical presentations; and, have two patents (applied) on stem cell and regenerative medicine for the isolation of stem cells. But the only publication evidence of work related to this list of claims we found was based on conference proceedings in the *Journal of Stem cells and Regenerative Life sciences and Biotechnology*. This is a non-peer-reviewed, free online journal, with its editorial office and headquarters in Chennai and Kofu respectively, the Indian and Japanese homes of Big Man.

In short, Big Man cultivates and maintains a large network in Japan and India that provides ‘Japanese’ stem cell technology to Indian therapists, whom ZCRM first trains and then charges for stem cell applications to patients, thus avoiding ethical entanglements, while closely following the progress made with treatment methods and technologies.

**Big Man as a boundary person**
To bring together Japanese technology with Indian patients, Big Man tries to match, in a way conducive to the expansion and efficacy of his bionetwork, the interests of Japanese business partners, Japanese and Indian therapists/researchers, Indian and Japanese officials and Indian patients. As a boundary person, Big Man persuades his contacts of the safety of his undertakings, his trustworthiness and the benefit of his services, while manipulating useful uncertainties.

Business partners in Japan

Big Man knows how to match needs with solutions that inspire trust. It is well known that foreigners in Japan are rarely accepted and treated as Japanese, and Big Man’s expression, gait, gestures, and overall appearance stand out as non-Japanese. But he claims that his fluency in the Japanese language, his marriage to a Japanese, and his Japanese livelihood and home make him as Japanese as the Japanese: ‘When in Japan, I am Japanese. The only time I realise that I am not is in the morning at shaving time, when I look in the mirror.’

Big Man’s Japanese collaborators confirm this: his affiliation to a Japanese university and his Japanese family-home induces trust, even though Big Man’s life is spent commuting between India and Japan. When asked why Japanese researchers collaborate with ZCRM, Big Man explains:

If I would go to them by myself they would not listen to me. But, because I have contacts with Yamazaki and others…. They were in need of getting research done
on some grafts for some studies abroad. I was there. I fitted in that particular puzzle to finish the project. Then you develop some confidence.…

Big Man explains that trust in him grew beyond Japanese borders through his knowledge and success:

Confidentiality and documents in third world country institutes are still in a development. From there on I slowly became in contact with a large group of people over the last ten years. Then they came to me and asked me ‘why do you not do this and that?’ And after seeing my research model in India, which is not a business model, but a research model, they became interested.

Trust, research and investment came together in ESCT. When Big Man was working on vascular grafts and corneas in Thailand, he established connections with Professor Arimori from Waseda. They have developed a series of materials, including polymers, used in stem cell therapies. However, in Japan, bureaucratic hurdles and a shortage of patients kept them from the quick success attainable in India:

We tried to develop them into a medical application, but that takes a long time. The approvals in Japan take at least 5 to 10 years. Drug discovery takes a long time…. But also some of the applications, even if you have the licence. You don’t have patients for those diseases…. Approval should be easier, and after the application you should be able to take back the money that you put into the research. (Interview, Big Man, 5 November 2008)
Big Man and his colleagues explicitly regard working with Indian collaborators as a solution to the Japanese tight regulatory regime. He met businessman Yamazaki in a hospital in connection with the fabrication and import of medical equipment. Yamazaki, an importer of medical equipment from South Asia, invited Big Man to teach medical English. On the day the first author met Big Man, he and Yamazaki were celebrating the formal registration of their business as a company (formerly only a licensed office) in Kyoto as Z International. They regarded the registration as confirmation of their recognition as a company. Explaining in English that this was possible because ZCRM plans to fund research in Japan, Yamazaki, who does not understand English very well, promptly said in Japanese: ‘We do not do [experimental] research in Japan, only in India.’ Big Man soon ‘corrected’ him by pointing out that ‘we need funds for the research of Origuchi Sensei [common honorific meaning teacher] from Todai [Tokyo University].’ Although businessman Yamazaki stands fully behind Big Man, he does realize that the technologies licensed to Indian clinics are not specifically developed by ZCRM; they are just waiting to be tested in Japanese laboratories. But Big Man wishes to present a balanced picture of the exchange between Japan and India, downplaying the fact that clinical research in India is one of the main drivers for Z-International’s ventures abroad. As will become clear, Big Man’s job as a boundary person is to preserve and maintain harmony between interests that serve the bionetwork.

*Japanese scientists*
Big Man taps Japanese resources in various ways. On the one hand, he uses newly
developed technologies that are not yet authorized by the government to licence to
hospitals in India. On the other hand, he capitalizes on the need of Japanese research
centres to experiment with their technologies on patients. The shortage of patients for
clinical experiments in Japan derives from the high standard of treatment covered by
National Health Insurance, which makes it less attractive for patients to pay for new
experimental treatments in private. Thus, in 2008 one government-sponsored research
centre in the Kansai area was waiting for a general hospital to be built adjacent to it, in
order to close the gap between newly generated technologies and clinical studies. In the
same centre a meeting took place with a high-tech institute in India. According to one of
the researchers present, a leading researcher suggested:

There is a good opportunity for collaboration, because the possibility of doing
clinical trials in Japan is usually limited by the number of patients. The doctor
there answered that ‘we have a lot of patients, and we have actually young
patients as well.’ That would be very interesting for Japanese studies. The
limitation there is probably money and other aspects. He said, ‘we have enough
money here, but not enough patients.’ But I do not know if anything developed
out of this. (Interview, Dr. Panto, 1 Dec 2008)

Although interviewees admit that they commonly entertain the idea of bartering between
patients and technology and investment (e.g., Egawa, interview 17 November 2008), such
exchanges are usually referred to as ‘collaboration’ and ‘scientific exchanges’, and
sometimes as ‘providing help’. Big Man speaks of such exchanges in terms of charitable activities, providing cheap treatment to Indian patients, and aiding Japanese patients who cannot find treatment in their own country, in both cases through reliable Japanese technologies in India (interview 5 Nov 2008; and see ZCRM’s website accessed on 22 Jan 2009).

Big Man is especially aware that testing the high-profile iPS [induced pluripotent stem cell] technology developed by Yamanaka Shinya from Kyoto University will require numerous patients. At the same time, it would be a great asset to young Indian researchers. For this reason, Big Man has arranged to have researchers from India trained at Kyoto University, and established connections with leading researchers working on future clinical applications:

I have met Dr. Yamamoto and Prof. Takeuchi for a couple of times. When we send some researchers there, they will be training them. Now he has proposed that we should start collaboration, send someone from India to do iPS research, and doing iPS research in India …. Now we have a meeting in Tokyo with him on 5th or 6th of March to make an agreement…. He is not sure if Kyoto will send its people to India, but Yamamoto has already been to India for a conference for a few days, so he already knows what is happening there. He was really impressed by the young powerful youth in India. (Interview, 5 November 2008)
When the first author met with Prof. Takeuchi in Kyoto, however, he flatly denied ever having heard of ZCRM or of Big Man. When asked what he thought of conducting experimental research abroad, Prof. Takeuchi responded:

It is wrong. Using Japanese people’s tax to create new applications not using it for Japanese people, but selling it to Americans .... No matter how you look at it, it is abnormal. Not keeping the diseases of the Japanese people in mind when developing new applications is strange (okasshi). (Interview, 30 October 2008)

This response was an attempt to steer the conversation away from Big Man while trying to express commitment to Japanese science. Though Prof. Takeuchi showed his Japanese patriotism vis-à-vis the USA, he had other concerns when considering testing ‘Japanese’ technologies in India:

If you can do good research and use proper equipment for the research in India, and if you can use it in Japan as well, then it would be OK. But [as they are different] you would have to do the experiments once again for the Japanese. (Ibid.)

He did not deny the possible acceptability and even advantage of having a link with Indian patients. Experimental data obtained in India are useful because they can provide arguments for permission from the PMDA to test new treatments in Japan. Even though the International Conference on Harmonization of Technical Requirements for
Registration of Pharmaceuticals for Human Use (ICH) has reduced the need to repeat research through agreements that recognize the validity of test results in member countries, Japan has been able to negotiate that, to a certain extent, clinical trials and experimental research conducted abroad have to be repeated in Japan for disputable reasons related to race and environment (Kuo, 2008). Consequently, and as argued by Japanese scientists such as Prof. Takeuchi, the availability of data from abroad can count as favourable evidence for seeking permission to conduct less extensive clinical research. Prof. Takeuchi’s refusal to admit any knowledge of Big Man, however, is a sign that he is unsure about whether Big Man will bring scandal, become a threat to scientists of good repute, or facilitate research. Similarly, a senior researcher in the same institute working under Prof. Takeuchi, Dr. Yamamoto, who actually had participated in a conference organised by Big Man, denied any connection with Big Man apart from knowing him as organiser of a scientific conference held in India. Although Dr. Yamamoto kindly explained to me all about his work on mesenchymal stem cell research applications to the knees (interview, 27 October 2008), any question remotely related to India was diverted to stem cell research applications of iPS. Little did he know that Big Man would place a photograph of him taken in India on the front page of ZCRM’s bulletin.

Confronting a scientist with the application of their technology to cases in India led to other ambiguous reactions. Big Man kindly introduced the first author to Dr. Umemura, whose immunology therapy, called AI, is licensed to Indian clinics. She asked Dr. Umemura questions about the following description of the case of Mr. Ali which appeared on the XIRM website:
The 25-year old Mr. Ali, who sustained an injury to his spinal cord in October 2006 at a construction site in Abudhabi, became bound to a wheel chair. In December 2006, he was admitted to the XIRM (of the SL Hospital Group), Chennai, for reparative surgery. The hospital had just signed a MoU with ZCRM, and it was decided to use the autologous stem cell technology developed by Dr. Umemura of AI-therapy Institute, Tokyo, Japan. Stem cells were isolated from his iliac bone, expanded and injected into the space around the injured site of the spinal cord …. Two months later, Mr. Ali was able to withhold his urine for up to 2 hours and could walk independently. At a press meeting in February 2007, graced with the presence of Mr. Otsuji, Consul of Japan, Dr. Raj presented the case to the audience.

When asked about the method he used on the spectacular case of Mr. Ali’s Spinal Cord Injury (SCI), Dr. Umemura said:

Even though the technology is based on publicised science, this [applying his method to SCI] seems to be out of control. I created the method for cancer application. Dr. Big Man, as far as I could see, was quite different. I cannot support the use of these technologies in India, for I do not know if accidents will occur. But if it goes out of control [causes a scandal], also in Big Man’s case, I withdraw my support. (Interview, 18 November 2008)
Although it is not clear if Dr. Umemura benefits from the licensing fees for the use of his technology in India, any scandal around his technology would damage his reputation and partnership with other Japanese clinics. When asked, Dr. Umemura clarified that his technology was not recommended for SCI cases. Furthermore, the AI technology used by ZCRM is for financial reasons limited to using so-called natural killer (NK) cells, while that in Japan is combined with Cytotoxic T Lymphocytes (CTL) cells. Moreover, the therapy, even if provided in its entirety, is not acknowledged as standard treatment in Japan. A meeting with Mr. Ali could shed light on the effect of the therapy. But when the second author asked SL Hospital for Mr. Ali’s contact information, it turned out to be lost.

Providing an inferior therapy in India would go against the spirit of Japanese regulation, which does not condone providing therapies abroad if they are not approved for Japan’s own people (interview, Egawa, 17 November). Nevertheless, Dr. Umemura knows about the likelihood of such applications in India, as photographs on the web attest to his visiting the clinic where the therapy was applied to SCI patients – Big Man needed the Japanese scientists as the faces of the technology he licenses out to Indian therapists for application to patients in India. Big Man’s task is to emphasize the charitable aspects of their collaborations, to celebrate international relations, and to declare the cause of science and developmental aid, while underplaying the licensing fees, experimental testing, and risk to patients.

*State institutions in India*
In India, ZCRM could benefit from the government policy in support of public-private partnership efforts, for which the Department of Biotechnology has initiated a new scheme called Small Business Innovation Research Initiative (SBIRI) (Express Pharma, 2006). There are many such initiatives in Indian academic institutes, hospitals and industries in the field of stem cell research and therapy. The government cooperates with private industry so that cost-effective remedies can be found, rather than struggling hard to find therapeutic solutions that then become expensive (Khan, 2007). But Big Man is not interested in acquiring such government funding:

> If you look at the funding, it is comparatively low. And most of the funding is going to the governmental institutes. A main consideration is not the funding, but confidentiality. For if you submit a proposal in India, it goes to 30 different people from 30 institutes, so it is no longer secret. It also takes a long time.…

(Interview, Big Man, 5 November 2008)

Rather than risking the leaking of research plans to Indian researchers in order to gain a limited amount of funding that is likely to go to Indian government institutes, Big Man prefers to rely on Japanese financial supporters, such as Mr. Arimori. In this way, the research remains among friends, and testing can be done in Chennai, where the costs of living, he explains, is about one fifth of that in Tokyo. Rather than seeking financial aid, Big Man seeks diplomatic support from the central authorities. On its website, ZCRM published the positive evaluations of research at ZCRM made by a visitation committee from AIIMS (All India Institute of Medical Sciences), which especially emphasised the
cleanliness and enthusiasm at the facility. The following message posted on its website gives the impression that ZCRM has received permission to provide stem cell therapies: ‘Since, it is just the use of autologous stem cells; there is no need for clinical trials. This is what the ICMR guidelines say’ (ZCRM’s website, accessed on 22 January 2010).

But when it is pointed out to Big Man that only bone marrow transplantation is allowed and stem cell therapies require registration, Big Man refuses to comment (telephone interview, BM 17 January 2009).

Officials are not unaware of this regulatory evasion. When asked about facilities and conditions at ZCRM, the Deputy Director of the Stem Cell Division of ICMR, Dr. Rama Gupta observed:

The basic research facilities in terms of infrastructure as per the requirement are not there at ZCRM. It is just a hut and they are just doing unethical business. Even the Director of the Centre is pleading with us and meeting us at Delhi several times, but we said no to give any approval to them for clinical trials. It is not up to the standard. (Interview, 26 November 2008)

But on its website ZCRM claims that during an ICMR visitation to ZCRM premises, the same senior official commented: ‘Highly enthusiastic committed team. Best wishes for achieving the goal.’
We also find ambiguity about Big Man expressed by individuals with state supervisory powers. Officials do not deny having visited ZCRM, and they even say nice things to them. In fact, we know that ICMR officials themselves are aware of ethically dubious practices in many stem cell therapy institutes but they do not have the capacity to pursue them without getting into trouble themselves (ex-ICMR official, Agarwal).

Collaborators in India

ZCRM also provides technical services related to stem cell isolation and processing to XIRM, a satellite clinic of the X Hospital Group in Chennai (see Patra and Sleeboom-Faulkner, 2009). Apart from providing therapies to test its ‘own’ technology, ZCRM also trains physicians to use the equipment for adult autologous stem cell therapy. The co-coordinator of XIRM (interview 5 November 2008) claims that, between 2006 and 2008, XIRM provided 470 patients with therapy for a variety of disease conditions, including SCI, liver cirrhosis, cardiac infarction and Alzheimer Disease. Though Big Man claims that ‘we are trying to develop some mechanism and therapies that will be made available to the poor and downtrodden people in India’ (telephone interview BM, 17 January 2009), XIRM says it receives patients from 20 to 25 different countries, including Australia, New Zealand, the USA, Japan, Pakistan and Sri Lanka. Patients from foreign countries are charged 15-20% more than are the Indian patients, because they require extra care during the treatment period. The collaboration between ZCRM and XIRM, however, was short-lived. In the second year of their collaboration, the SL Hospital Group upgraded its stem cell research facilities and became self-sufficient. When it started conducting stem cell isolation, processing and clinical administration
independently, the technical tie-up with ZCRM came to an end, and XIRM had become ZCRM’s competitor.

The Indian collaborators of Big Man, unlike the Japanese collaborators, had no problems confirming their current and past relations with ZCRM. Using similar technologies and having its own patient pool, XIRM had used Big Man’s services to the fullest extent, and then decided to become independent. Being technologically self-sufficient, and having no concern for scandal-ridden Japan, XIRM had no need for charitable sentiment like that expressed by Big Man. Though India has its own scandal press, ESCT is variously seen as a saviour, a sensible option, a disappointment, or a cheat. Such variety of opinion does not lend itself to moral outrage easily. And, even when it does, such as with the human embryonic stem cell therapy of Geeta Shroff in Delhi, the survival of her institute proves this does not mean the end of the enterprise, as it would in Japan.

*Patients in India*

The present study examines the bionetworking activities and values of Big Men by focusing on a case study of ZRCM’s Big Man. We have described patient experiences in other writings (Patra and Sleeboom-Faulkner, 2009; 2011), and so in the remainder of this paper, we shall only mention some of the difficult choices among available therapy options faced by patients affected by SCI. The second author met a patient with SCI, whom we shall call Sanju, in the regenerative medicine department of a Chennai-based multi-speciality hospital. This hospital claims to have cured more than 400 patients in the past two years for ‘untreatable diseases’, by using adult stem cells. When the older
brother of the patient, Manas, was asked about their experience with stem cell therapies, he gave comments on the treatment in various hospitals:

There is a loot mar (cheating) going on in the name of stem cell therapy. Private hospitals like SL are just looting …. They decide how much to charge you by looking at your face. There is no fixed treatment charge or a transparent system in place anywhere, so we do not know if the therapy is really so expensive. We just have to pay, as we have no choice…. Dr. Girija is more of a hardcore businesswoman. She charges 1,500 rupees (US$40) just to give you an appointment and to discuss your condition before taking the therapy. When I met her for the first time, I paid 1,500 rupees but could speak with her only for about two minutes. About my brother’s problem, she said, ‘there is zero guarantee but 100 per cent effort; the success rate is around 80 per cent’. This type of statement is quite puzzling. We had to give in and spent around 5.5 lakh rupees (approximately US$12,000) in six months’ time on treatment and related expenditures…. (Interview, 24 November 2008)

Patients and their families are overwhelmed by hope, desperation and uncertainty. This makes them vulnerable to extortion, not simply because they are unable to judge the science, but also because they see science as the only solution to their problems. Sanju also tried public healthcare:
Our experience at AIIMS is quite different. At government hospitals nobody cares. They do not say anything to you unless you have some connections; if you know some people, some doctor or a politician, you can get a bed. To me they said, they do not provide stem cell therapy for spinal cord injury, but I read in the newspapers that there is a trial going on at AIIMS for various conditions including spinal cord injury. (Interview, 24 November 2008; translated from Hindi by PKP)

This family gave up its search for treatment due to ‘financial exhaustion’, but this type of customer is among the most likely recruitment targets for the bionetworking activities of Big Men, as discussed in the next section.

One of Big Man’s collaborators, XIRM’s SL hospital, managed the recruitment of patients for ZCRM, using what we call ‘recruiter patients’ (Patra and Sleeboom-Faulkner, 2011). Mr. Patel, a SCI patient from Gujarat, contacted SL Hospital to enquire about stem cell therapy after he was unsuccessfully treated elsewhere. Desperate for guidance, he wrote an email to Dr. Rajiv, the head of the stem cell section at SL Hospital. Rajiv advised him to speak with two patients who had been successfully treated for similar injuries. Patel appreciated the feedback about the treatment and the hospital, and decided to undergo therapy at SL Hospital. But, after a while, he became suspicious of the ‘patients’, believing that the voices of the coordinator and the patients were one and the same. In his website blog Patel observed:

A while back I spoke to Mr. SR who is a coordinator of the stem cell department in Lifeline hospital. Something was very fishy; the voices of Mr.
SV (the patient) and Mr. SR seemed very similar. So I went to the website and checked the Contact us section. I was so hurt to see that Mr. SR’s number on this page and Mr. SV’s number on the above e-mail were the same. (Patel blog, 8 February 2007)

So, not only are ‘incurable’ patients attracted to ESCT providers, they are also actively recruited through manipulative bionetworking, and are forced to face health dilemmas that regularly lead families to bankruptcy.

Big Man sustains his bionetworking by manipulating three sources of uncertainty in relation to the people he needs to maintain connections with: first, the uncertainty around the efficacy of ESCTs; second, the variable reputations of regulatory regimes in different countries; and, third the variable concerns scientists have when getting involved with ESCT. To assuage these uncertainties, Big Man makes full use of the reputation of Japanese science and technology, his familiarity with regulatory regimes and his connections with officials, his link with charities and role as philanthropist, and his substantial interest in and knowledge of science innovation. He uses diverse aspects of his history, physique, linguistic, cultural and scientific knowledge, and science and business networks to inspire trust in his ability to succeed. But their collaborations with Big Man leave business partners, patients, regulators and scientists with their own dilemmas and ambiguities. These are discussed below in relation to biohierarchies.

Discussion: Biohierarchies
The fact that Big Man met one author in Japan and not the other in India is in character with his efforts, in scandal-prone Japan, to display the ethical, legal and financial sensibility of ZCRM’s activities. The second author saw the surliness of ZCRM’s coordinator in the Indian hunting ground for clientele. Big Man’s bionetworking activities express a range of preferences and values related to people’s health needs, the pursuit of knowledge, profit making and reputation. To understand the priorities of these values in Big Man’s bionetworking activities, we found it instructive to set out his main concerns regarding the needs of patients (see table 1). We did this by listing the arguments he used for bringing together research, technology and therapy in scientific collaboration between India and Japan. The arguments ranged from data on regulatory advantages and numbers of available patients to the ability of patients to pay, the ways in which they are insurance, and advantages for Japanese and Indian scientists.

Big Man observed that not many patients in Japan are available for ESCT; Japan’s guidelines only allow autologous ESCT in cases of serious, incurable disease, and since 2006 separate guidelines have been developed for Adult Stem Cell Research in a Clinical Setting (see table 1, level 2). Although Japanese patients are well covered by state insurance, they do not always have access to suitable innovative therapies, already recognised in, for instance, Europe (level 3). In fact, they can be in worse situations than their Indian counterparts, who, if blessed with funds, can access the newest therapies locally (level 5). However, both Japanese and Indian patients are potentially interested in ESCT when the standards of the therapy are questionable (levels 4 and 5), as seen in the
examples of Sanju and Patel above. Big Man is aware of these patient needs and regulatory restrictions:

Before Japanese patients go abroad [level 4] they first exhaust their possibilities [level 1-3], while Indian patients, who usually have no adequate health coverage, spend private means to purchase therapies of uncertain quality at home [level 4-5]. Other patients without money we can help as well through our charity (level 6). (Interview Big Man, 17 January 2009)

Big Man formulates these needs and gaps in terms of charity, scientific progress and business concerns. The biohierarchy creates such meanings on the basis of potential surplus obtainable through the manipulation of inequalities and knowledge of them.

Though trust is part and parcel of his bionetwork, we found substantial discomfort with and disloyalty towards Big Man among nearly all associates. Being aware of the existence of biohierarchies, Japanese researchers are tempted to ‘help’ Indian patients and to ‘train’ Indian therapists. At the same time, scientists’ efforts to distance themselves from Big Man’s activities indicate that they are torn between the need to protect their reputation and the ambition to further their research. In addition to the medical and financial vulnerability that is exploited through bionetworking activities, the biohierarchy also seems to inspire a near-missionary quest for biomedical knowledge and its translation into therapies.
Conclusion

Observers have contrasted the free market approach, in which doctors and rogue entrepreneurs exploit patient trust to make profit, acquire glory, or advance experimental medicine, with a robust regulatory framework and monitoring (Kiatponsan and Sipp, 2008). But ESCT combines the efforts of reputable scientists working under tight regulatory supervision in one country with the work of scientists of unknown reputation providing commercial therapy to ‘available’ patients in another. It should be reiterated that providing therapies to incurable patients under free market conditions, though not supported by the state in either India or Japan, is not illegal in either country.

The value of Big Man’s skills are inflated in the unregulated transnational space of transaction between Japan and India. He would be nowhere without the widespread belief in the ability of ‘modern’ (here, Japanese) science to save the incurable. Ironically, it is the absence of Western scientific spirit that is thought to explain the ‘success’ of stem cell therapies in India (Bharadwaj and Glasner, 2009). The double bind of India’s being an underdog in ‘neoliberal globalisation’ and the belief in the benefits to India of Western biomedicine leads ICMR both to criticise Big Man for his unethical practices, and also to hope that medical progress will result. The fact that from 2003 to 2006 AIIMS conducted, without ICMR vetting, a multi-centred clinical trial using stem cell therapy (Hindustan Times, 2006), makes it hard to differentiate between the ethical practices of private and public research, and possibly even harder to reject potentially innovative therapeutic applications that attract money, technology and training capacity in the midst of the optimistic exuberance of the stem cell research boom.
In the end, the biomedical ethic unites Big Man and his associates and facilitates his work as a boundary person. Big Man’s enthusiastic dedication to charity and scientific progress embodies a biomedical ethic that is shared, despite the different ways in which it refracts in the lives of scientists, patients and officials. And although it is the ‘rational’ logic of biohierarchy that calls for business to ‘fill the gap’ between demand for healthcare and supply of therapy, it is the spirit of bioethical capacity building, medical charity, biomedical efforts and scientific discovery that unites Japanese partners, scientists, therapists, patients, and the ICMR in Big Man’s global bionetworking strategies. In this transnational space of transaction, Big Man’s bionetworking thrives on the manipulation and transgression of regulatory, scientific and ethical boundaries. While nurturing a biomedical ethic of charity and upholding a high level of bioethical correctness, Big Man’s bionetworking draws on but does not draw attention to the serious health and wealth inequities across borders that enable these ‘philanthropic’ dealings.

Notes

i We have used pseudonyms for the names of individuals, clinics, hospitals and places to avoid the identification of individuals and to divert attention from hospital and company names, as we aim to examine social phenomena rather than particular people and companies.

ii ZCRM has research collaborations with many small Indian institutes and hospitals: the Vision Research Foundation, Sankara Nethralaya, Chennai; The Centre for Liver Research & Diagnostics, Owaisi Hospital, Hyderabad; the Aditya Jyot Eye Hospital, Mumbai; the Institute of Ophthalmology, Joseph Eye Hospital, Trichy Cell Therapeutics; the Dept. of Sports Medicine, SRMC & RI (DU), Chennai; the Department of Molecular
Induced pluripotent stem cells are a type of pluripotent stem cell made from somatic cells by inducing the expression of specific genes. As compared to human embryonic stem cells, somatic stem cells are easy to come, are less prone to immune rejection, and are not as ethically controversial, iPS are hoped to facilitate clinical applications in human diseases.

Using CTL cells is expensive, as it requires special equipment. According to the developers of the therapy, it is disputable whether the use of NK cells alone is sufficient, increasing the chance of developing infection.

In Japan private clinics can provided any therapy as long as the patient consents. But for most scientists this is not an option, as such experimental therapies are not insured. Moreover, scientists put their reputation (and funding) at risk when they engage in dubious practices. Data garnered from trying out therapies in India are hoped to facilitate the authorization of clinical trials in Japan.

References


*Hindustan Times* (2006) Stem cell trials to start at AIIMS. *Hindustan Times*, 13 November,


Biographical notes

Margaret Sleeboom-Faulkner is Reader in Anthropology at the University of Sussex. She is the author of articles and books on academic nationalism in China and Japan and on biobanking and genetic and predictive testing in Asia (see www.sussex.ac.uk/profiles/192052). Currently she is conducting research on ‘Bionetworking in Asia’, which concerns the study of the nature of international science collaborations.
Prasanna Kumar Patra is Reader in Anthropology at Utkal University, India. His work focuses on the interface between socio-cultural and biomedical dimensions in stem cell science and biobanking in India and Japan. He has co-authored a book entitled Demography and Development Dynamics in a Primitive Tribe of the Himalayas and has authored publications in international anthropology and ethics journals.