

State of the Art Report on Stem Cell Travel

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Introduction

Stem Cell travel¹, commonly referred to as ‘stem cell tourism’, is a relatively new phenomenon that has already garnered significant interest from a large field of actors. The aim of this report is to provide a state of the art outline of the issue by sketching the issues background and provide an overview of some of the conceptualizations that have been produced thus far in academia and various state and media entities. This report is part of the project *the Human stem cell: Health, Hope, and Bio-Economy*; an interdisciplinary project under the direction of Professor Susanne Lundin whose goal is to begin researching the entanglements between medicine’s strive to create health through human stem cells, cultural imaginations about scientific progress, and the commercialization of health and human biology (Lundin, 2013). In addition, the project further develops previous studies from the research team on the commercialization of the body and the formation of ethics from stem cell researchers as individuals in society (see Lundin, 2012; and Lundin, 2010); and creates new ways to explore links between globalization and the inter-articulation of travel formations (see Humbracht, 2012) The project is funded by **The Erik Philip-Sörensen Foundation**. The report will begin by summarizing the issue and delineating the context in which stem cell travel has developed, then move on provide an overview of the approaches taken by various actors who have begun to investigate stem cell travel.

Stem Cell Travel – Background

Stem cell travel refers to a form of medical mobility where patients from around the world travel to clinics to be treated with unproven or experimental stem cell interventions for a wide variety of neurodegenerative diseases and debilitating disorders. Examples of diseases and disorders include Parkinson’s, multiple sclerosis, amyotrophic lateral sclerosis, Alzheimer’s, cerebral palsy, optic nerve hypoplasia, and spinal cord injuries (Chen and Gottweis, 2011; Einsiedel and Adamson, 2012). The clinics employ a range of stem cell types including adult allogeneic and autologous, embryonic and fetal stem cells, and administer procedures using surgical, oral, topical and intravenous techniques; treatments are often similar despite diseases or conditions having distinct etiologies (Master, Zarzeczny, Rachul, and Caufield, 2013). Since it’s beginning stem cell travel has been steadily increasing with clinics opening in Europe, North America, Central America, Africa, Asia, and the Caribbean. The majority of clinics are able to offer stem cell therapies that have not passed clinical trials by taking advantage of gaps in regulatory systems or weak oversight by state actors (Mummery, Wilmut, Van De Stolpe, and Roelen, 2011; Daley, 2012). While there are

numerous examples of this form of exploitation in developing nations like China and India there are also many examples coming from more developed nations like the Netherlands, Germany, and the United States (Enserink, 2006). The general increase, however, in attention and concern over stem cell travel has led to efforts to strengthen regulatory systems effectiveness and attempts to force clinics to either prove the efficacy of treatments or face closure. These efforts have produced some success both in developing and developed nations. In China, Costa Rica, Hungary, and Korea for example, pressure to step up regulations has led to further oversight in clinical practices (Gottweis and Chen, 2011; Master, Zarzeczny, Rachul, and Caufield, 2013). In Germany, the XCell center in Dusseldorf was forced to close after the death of a baby (Mendick and Hall, 2011). In the Netherlands, the preventive medical center, and in the United States, CellTex, were both forced to close by government regulatory bodies for administering treatments that had not been proven through clinical trials (Enserink, 2006; Cyranoski, 2013). Stem cell clinics have, however, demonstrated an ability to resist regulation, revealing that creating global regulation of stem cell therapies is highly problematic and remains largely at a level of the political drawing board. This is due, in part, to that fact that stem cell travel has developed in a context of increasing globalization where companies, and other public and private institutions, follow a model of 'flexible accumulation' by forming partnerships that enable them to assemble scientific knowledge and technology in order to find new sources of value (Gottweis, Salter, and Waldby 2009; Isasi, 2009). These kinds of knowledge economies form what anthropologist Arjun Appadurai has termed technoscapes (Appadurai, 1996). These are circulating flows of technology that land asymmetrically in localities creating social and political fissures through the formation of new material, technological, economic, and socio-political constellations. As technology, and the accompanying competencies, are folded into localities these localities align themselves with techno imagined communities by attempting to build themselves into biomedical knowledge nodes, who are increasingly in competition, and that operate along fluid globalized networks that often subvert the influence of the nation-state. These processes of dis-aggregating and then re-aggregating biotechnology and biomedical knowledge so that they can flow along global networks have several advantages: Firstly, the costs of production, development of necessary infrastructure, obtaining intellectual property rights, and distribution of risk to operate stem cell clinics can be strategically divided between stakeholders (Patra and Sleeboom-Faulkner, 2009; see also Wahlberg and Streitfellner, 2009). Secondly, in many cases this allows for stem cell clinics to promote themselves as knowledge centers, or destinations, by creating packaged trips that can be organized between partners across

transnational space. Patients can buy trips in a similar way that a leisure tourist would buy a packaged trip to a popular resort destination. This is the case with Medicare Tourism, a tourism operator based out of Oman that sells medical tourism packages, including stem cell treatments, in destinations around the world. Lastly, stem cell clinic's ability to be flexible and divide risk and resources make regulating stem cell travel complex and arduous. As stem cell clinics are often constructed through networks of clinics where treatments are organized in one location and carried out in another, this permits fewer problems with government regulation; or once pressure is put on clinics to close, they simply up and move to a country where regulation is less stringent. This was the case with the Cell Medicine clinic in Costa Rica that was forced to shut down but then moved to Panama City where it could operate unhindered (Einsiedel and Adamson, 2012).

Stem cell clinics increasing ability to make contributions to developing local economies also plays role in curtailing regulation efforts. As nations, regions, and cities across the globe largely see themselves in competition to leverage their ability to impact scientific research and build knowledge centers (Gottweis, Salter, and Waldby 2009), this can translate politically into diluting regulation on stem cell therapies. In China, for example, the largest stem cell operator Beike biotech has largely been able to conduct stem cell treatments despite increasing regulation from the state ministry of health. This is in part due to the hope of both the state and Beike that the company's operations will one-day spawn a competitive advantage for the Chinese bio-economy (Gottweis and Chen, 2011).

The development of stem cell research in one context is also largely connected to the regulatory environments in other contexts. Stem research has an enormously controversial standing in many countries around the world. Due to ethical concerns, many nations have significantly limited the legal status of stem cells research and others have banned it all together (Mertes and Pennings, 2008; Frunza, Gavrilita, and Ioan, 2012). For physicians who find themselves charged with generating research funding in an increasingly competitive and commercialized health environment, the limits placed on them by their governments on ethical grounds places even more pressure on them to legitimate stem cell research. For nations where stem cell research is legal, there is often the perception that stem cells are an opportunity to get a head in the development of health centers operating in a globalized landscape.

Supply is, however, only one element in stem cell travel; demand is another critical factor driving this form of bio-economy. Patients from over sixty countries travel to seek out stem cell treatments, with the largest flows coming from the US, the UK, Australia,

and Canada (Song, 2010; Master, Zarzeczny, Rachul, and Caufield, 2013). Patients pay a fee that can range from \$5,000 to \$80,000 (Lau et al, 2008; Enserink, 2006). There are several motivations that have been found to guide patient's trips. First, distrust or frustration with local or national healthcare systems combined with perceptions that healthcare and the development of medical treatments are sluggish, lagging behind, or bogged down by incumbent political authorities (Song, 2010; Master, Zarzeczny, Rachul, and Caufield, 2013; Rachul, 2011). Importantly, many patients view their trips abroad as a last hope in the battle against a debilitating or potentially fatal disease. This hope is reinforced by hype from stem cell clinics in their use of internet based direct-to-consumer marketing, with often advanced advertising strategies, that often over emphasizes the potential healing power of stem cell therapies (Petersen and Seear, 2011). Hype also has come from scientists, bioethicist, politicians, and journalists who over the past decade have enthusiastically portrayed the potential of stem cell research (Devereaux and Loring, 2010). The reasons for this enthusiasm range from genuine idealism and optimism to practical realities of modern science that must simultaneously conduct rigorous research while also attracting industry and government funding by producing results that are clinically and commercially viable (Murdoch and Scott, 2010).

Another key area where hope is mobilized and distributed is through patient blogs and on-line communities. These on-line public spaces act as sites in patients networks that allow past, present, and future patients to access information, raise funds for trips, share and contrast options, assess clinics and treatments, and build personal and collective narratives that form the bases of community (Gottweis and Chen, 2011). Patient networks are organized on-line but have very real consequences offline, as they allow patients to overcome obstacles that might otherwise hinder stem cell travel while also re-defining the social dynamics of patienthood; a dynamics that play a large role in generating the necessary hope that makes participating in stem cell therapies that are expensive, unproven, and potentially dangerous. Thus, an important layer of stem cell travel is an economy of hope and hype that forms a constitutive process of value creation in healthcare. This economy is fuelled and interconnected with the commercialization of health, but also a cultural backdrop of pervasive interest in regenerative medicine, escaping death, dying, decay that is manifested in popular cultures fascination with plastic surgery, makeup, vampires, and the fountain of youth myths (Murdoch and Scott, 2010).

Research and Discourse on Stem Cell Travel

In academia multiple disciplines have approached stem cell travel; both within their own disciplines and in cooperation with others'. The primary bulk of the research has come from medicine, philosophy, ethics/bio-ethics, and law with other disciplines such as anthropology, sociology, political science, and communication studies making important contributions. A majority of the debate about stem cell travel and how to conceptualize the issue has come via scholars who argue the phenomenon needs regulation and how to best achieve this regulation (see for example Hyun, Kindvall, et al, 2008; Kiatpongsan, and Sipp, 2009; Shalev, 2010; Master and Resnik, 2011). The International Society for Stem Cell Research (ISSCR) took an early lead in defining the dangers of stem cell travel and delineating how and why it needs oversight. The ISSCR created both *guidelines for the clinical translation of stem cells* and the *patient handbook on stem cell therapies*. The guidelines were designed to protect patients and reduce the perceived delegitimization of stem cell research resulting from unproven therapies; this was done by delineating what constitutes legitimate stem cell research that would form the basis of an overarching global framework for all clinics to follow when creating stem cell treatments. A later article published by Lindvall and Hyun, members of the ISSCR, expanded on arguments in the guidelines by stating that stem cell regulation has to block unproven therapies but also leave room for innovation that can produce valuable stem research (Lindvall and Hyun, 2008). The paper presented an important dichotomy of medical innovation versus stem cell tourism and tensions between physicians need to consider the best interest of the patient while also conducting legitimate stem cell research. Responses to the article have varied with many recognizing the need for innovation but who have argued that innovation is difficult to define and thus the majority of academic and policy attention should be focused on creating effective regulation (Cohen and Cohen, 2010a and b).

Several scholars, however, have argued that regulating stem cell treatments will be an enormously complex undertaking. Indeed, the implications for how to regulate stem travel makes up the majority of literature on stem cell travel. As mentioned in the introduction, the creation of stem cell treatments is developed both through, and within, global and local economic and political economies that take advantage of regulatory gaps making them highly resistant to multiple levels of regulatory governance. Stem cell centers are able to develop treatments by creating and maintaining networks of exchanges with collaborative bodies situated in local, national, and global relations; relations that often take advantage of, and build, local and global hierarchies that exacerbate social, political, and

economic inequalities (Patra, Sleeboom-Faulkner, 2010 and 2012). What's more, notions of hope and hype increasingly complicate drafting regulation in this context. Ethicists Murdoch and Scott argue that increasing patient autonomy combined with the power of hope may in fact trump well-reasoned and strategic attempts to hinder stem cell travel. In addition, they warn that regulation that is incautious and guided by paternalistic attitudes may in fact damage legislators ability influence stem cell travel by alienating patients and driving critical information about stem travel underground (Murdoch and Scott, 2010). The two scholars also importantly bring to the foreground the role many medical scientists have played in creating the hype around stem cell research and pointing out that stem cell clinics conducting unproven treatments have been able to capitalize on that hype. They argue that regulation is extremely important for patient protection, however, when developing regulation what is needed is more reflexive awareness of the role clinicians play in creating understandings of stem cells and also recognize that in many cases stem cells research practices at clinics abroad may not be medical charlatans but the result of culture-historical, economic, or philosophical difference (Murdoch and Scott, 2010). Philosopher Haiden Chen echoed this argument by stating that western characterizations of the regulatory environment in China as the "wild east" are inaccurate, politically loaded, and lacking empirical evidence. Instead, Chen argues the regulatory context in China should be described as a series of complex and individualized regulatory strategies by a variety of stakeholders (Chen, 2009). The literature here points out that when creating regulation attention should not only focus on patients, but on how patients, medical researchers, and a variety of actors each have a multitude of interconnected and potentially contradictory interests and perceptions of health that are generated from, and generative of, the situatedness of each actor in bio-economies that cross local and global borders. If regulation is to work, a more detailed and reflexive understanding of these relationships and the interconnectedness of actors are needed.

The power of hope provoked debate in academia and has been generally accepted. Some responses refuted Murdoch and Scott's thesis by reasserting the need for regulation and imply that regulation does not inherently mean treading on the hopes of patients (McMahon and Thorsteinsdottir, 2010; and Sipp, 2010). Nonetheless, a significant amount of attention has shifted to how to understand patients, and how physicians and regulators can act in parallel to those understandings. It has been recognized that more sensitivity is required to the different types of patients: patients ranging from children to adults, to those suffering from terminal illness or others who have less severe problems like a shoulder injury (Caulfield and McGuire, 2012). Physicians obligations, thus, will vary on a

case-by-case basis depending on the different kinds of patients (Levine, 2010), with perhaps more legal obligation to children (Zarzewny and Caulfield, 2010); and considering different shades of hope exist (Guest and Anderson, 2010) in different life contexts, these notions of hope will also require different strategies from physicians and regulators.

Considering the different kinds of patients and powerful motivations to seek treatment abroad (that were listed in the previous section) there have been calls for more information about patients trips to clinics abroad that can then be used by doctors and regulators to better inform patients about the potential risks and benefits of those stem cell treatments (Pepper, 2012; Master and Ogbogu, 2012; Dolan, 2010; Regenber, 2010, Kim et al, 2013)). Ryan and co-authors put forward the idea of creating a tracking system operated by a third party (not by patients or regulators) where patients would report the details of their treatments and follow up information on their condition (Ryan, Sanders, Wang, and Levine, 2010). The fact remains that while there have been known examples where unproven therapies have harmed patients (Amariglio, et al, 2009; Dedmon, 2009), there is still relatively little information about what happens during stem cell travel and the potential health risks and benefits that follow. Clinics that sell unproven treatments largely underrepresent the dangers; this means that potential stem cell travellers still have little real information about how dangerous treatments can be.

How to inform and engage patients also requires more sustained research about how to conceptualize patients and the roles patients play in bio-economy. In most of the articles written about stem cell travel patients are overwhelmingly painted as consumers of medical science. Anthropologist Priscilla Song has taken issue with positioning stem cell travel as tourism and characterizing patients as tourists, she argues that “the fundamental association of tourism with leisure renders it a problematic term to describe the experiences of patients who often feel forced to travel in order to seek the medical care they desire or need” (Song, 2010, p.386). In order to bring into focus the difficulties that patients experience and resist a patient-tourist paradigm, Song argues patients should be viewed as biotech pilgrims. This framework sheds light on changes in globalization and bio-economy that sees the juxtapositioning of flows from the third-world to the first-world. Despite this important analysis, however, tourism has remained the category that frames patient’s medical mobility in stem cell travel. Gottweis and Chen, for example, offer a contrasting view of patients; they sustain that patients should not be viewed as lonely individuals searching out treatment options but instead are people operating in stable patient networks that develop opinions and assess treatment options, that play an increasingly active role in managing their own health,

are willing take more risk, and challenge the authority of medical institutions. They take this as evidence that patients are more and more becoming consumers of health, and as consumers, patients take on a multitude of different roles as patients, funders, as research subjects. These roles they argue legitimize stem cell clinics that enable some to conduct treatments on a massive scale; a scale far outside the borders of proper medical innovation as argued by Lindvall and Hyun (Chen and Gottweis, 2011). They conclude by arguing that if patients are in fact proactive consumers taking responsibility for their own health than tools to combat stem cell travel like global regulation, ethical condemnation, or informational frameworks will have little effect.

In a study of online advertising techniques of stem cell clinics Petersen and Seear have also argued that because patients are consumers information campaigns would likely be unsuccessful. They argue that Ryan's argument of tracking stem cell patients is based on the assumption that patients are rational actors and not consumers whose emotions are targeted and manipulated by well-tuned marketing strategies (Petersen and Seear, 2011) Other studies have also cast doubt on the potential for physicians and regulators ability to combat stem cell travel. Einsiedel and Adamson conducted research into the general population's perception of stem cell travelers and the likelihood that the public would partake in treatments themselves. The study found that participants showed sympathy for patients who sought treatment abroad despite lack of evidence of the efficacy of treatments and the potential risks that follow (Einsiedel and Adamson, 2012). In addition, participants also suggested that they themselves would consider the possibility of medical travel in desperate circumstances despite having cautionary information. These findings could be connected to changing perceptions amongst the public that science and bio-technology do, and will continue to have in future, the ability to extend life expectancy and that this extension is favorable. This research marks a change with previous research that suggested the public was more or less ambivalent towards biotech's ability to extend life (Dragojlovic, 2012). Furthermore, this research points to the need for further investigation into the connection between ageing and perceptions of biotech, how perceptions are framed, in which contexts, and how they are redistributed.

It should be noted that while a considerable core of academic research has spelled out the difficulties for influencing and regulating stem cell travel none of the researchers have been so blunt as to call these efforts a lost cause. Much of the above research has delineated the problematic nature of creating regulation in a context where notions of health are guided by tensions created by both physicians and patients due their positioning in

knowledge economies of circulating bio-technology; a key component of which are political economics that construct and conflate dichotomies of hope and hype. A majority of researchers in fact argue that efforts to better inform the public, build public trust, and regulate stem cell travel face major challenges, but should nevertheless not be abandoned (Master and Resnik, 2013).

Recent research into websites that provide information for patients found that the available information and strategies for delivering this information is out of touch with current patient perceptions of medical health and their motivations for stem cell travel. In general, more patient outreach is needed, and more information on the pace, nature and challenges associated with the clinical translation of stem cell research (Master, Zarzeczny, Rachul, and Caulfield, 2013). This research indicates that more investigation is needed on the changing nature of the doctor patient relationship, the doctor's role in influencing decisions to partake in stem cell travel, and the ability to engage the hopes of patients (Feudtner, 2010; Levine and Wolf, 2012). Doctors require more reflexive and applied research that could better facilitate the creation of tools that more effectively assist them in understanding how to help the management of patient health.

Notes

¹ In this report the term 'stem cell travel' is used. Any use of the term 'stem cell tourism' is to describe how the phenomenon has been positioned in differing contexts. This report agrees with research (Song, 2010) that suggests tourism is a highly problematic term to describe this form of medical mobility. The use of the term tourism is deeply connected to how stem cell travel is being morally grounded in complex series of interconnected relationships (see Cresswell, 2006) in academia, and elsewhere. Thus, in order to avoid participating in the moralizing of the argument the much more neutral (but granted not unproblematic) term 'travel' is employed.

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