At the age of 60, Joe Woolfolk, 70, of Dallas, Texas knew he was dying. Multiple heart attacks in his mid-40s followed by a period of clinical death during cardiac bypass surgery in 1990 had destroyed nearly one-third of his heart muscle. Following his bypass, Woolfolk recalled hearing his doctors inform his wife, and high school sweetheart, he would not make it through the weekend. "I thought, 'I'm 45 years old - I've worked hard all my life, and I'm just going to lay here and die?!' To me, that was unacceptable." Resiliently stubborn, within a week, much to the surprise and chagrin of his cardiologist, Woolfolk was back at work. At this point, having survived their initial expectations, doctors gave Woolfolk 2-3 years to live, optimistically.

Nearly 16 years later, Woolfolk finally realized his heart was getting worse, "my time had run out but I didn't feel like dying. I was sleeping most of the time. I had very little energy to do anything. And because I couldn't do anything, I kept gaining more and more weight." A former professional golf instructor and avid cyclist and runner, Woolfolk could barely find the strength to walk 50 yards with a walker without becoming short of breath. With an ejection fraction of less than 20%, Woolfolk was in congestive heart failure, a condition that affects nearly 6 million Americans, commonly restricting their activities and leaving them bedridden. In March of 2006, Woolfolk had a defibrillator placed and was told by his doctors “the defibrillator was the very last thing that could be done for (his) condition.” By the summer of 2006, most doctors had written him off. However, the weakness in his heart could not affect Woolfolk's will to live. In December, he said, he made a decision to live.

That is when a friend told Woolfolk about stem cell therapies to regenerate damaged heart muscle. Woolfolk turned to the Internet for further research and discovered Theravitae, a private multinational stem cell therapy company that specializes in treating heart attack victims, congestive heart failure patients, and coronary artery disease patients with stem cells taken from the patient's own blood, using their VesCell technology. A key aspect of VesCell therapy is an advanced cell isolation and expansion technique that allows for adult stem cells to be harvested from blood collected in a procedure similar to a common blood donation.

Woolfolk contacted Theravitae and within days made the arrangements to travel to Bangkok, Thailand. “I contacted my cardiologist and was advised not to even think about going out of the country, especially Thailand. He said it was too experimental and hadn't been proven. Also, due to my medical condition, the trip would be too strenuous for me to attempt and was really dangerous.” However, Woolfolk has never taken ‘no’ for an answer. Upon his arrival on December 2, 2006, doctors drew a pint of his blood and sent it to Israel to a lab where his stem cells were produced over a week's time.

On December 9, Woolfolk received 30 heart injections with 6.2 million of his own adult stem cells in a minimally invasive surgical procedure at Bangkok Heart Hospital. "I have been in and out of so many hospitals throughout the years, but it was the best, most modern and cleanest hospital I have ever been in. Dr. Kit Arom (Chief Cardiothoracic Surgeon of Bangkok Heart Hospital) and Dr. Permyos Ruengsakulrach are two of the best doctors I have ever seen."

According to Woolfolk, the results of the procedure were immediate. Fourteen hours after surgery, Woolfolk was up walking and the following day rode a stationary bike and walked on the treadmill for 30 minutes each. "It was incredible. The next day I walked and rode for an hour!" Two weeks after returning to Texas, Woolfolk was back on the green and planning a fishing trip to Mexico with his son for the following month. "I was able to play 18 holes of golf in one day. Before the procedure, I could not even leave the house much less play golf! Now I have a new mission; to help people live. This may not be for everyone, but it's worth looking into."

Since the therapy, Woolfolk has seen the quality of his life skyrocket. "I said before I left for Thailand that if I get just one quality year of life from this stem cell therapy, it will be worth it." At nearly 8 years out, Joe's ejection fraction has peaked at 40% and has remained steady at 30%, up from less than 20%, prior to having his adult stem cell therapy.

To reaffirm his faith in stem cell technologies, Woolfolk recently traveled to Argentina in September of this year to have another series of stem cell injections, this time taken from his bone marrow and injected into his heart as well as his pancreas to treat his diabetes. "This time I wanted to have injections in both the remaining damaged heart muscle as well as my healthy heart muscle. Additionally, because I have type 2 diabetes, I had my pancreas injected as well." Not to break with tradition, Woolfolk walked out of the hospital the next day and returned home the day after.

Woolfolk is now a devout believer in stem cell therapy. Because of his procedures, he believes, he is now able to share his journey and introduce others to the possibility of surviving a damaged heart. "I'll speak to one person or 10,000. There is an alternative to dying, and people should know that."

Medical tourism has become an increasingly prominent sector of contemporary healthcare. For those willing and able to pay, undertaking travel to receive treatments that are either unavailable or more expensive where they live may be an attractive option. In recent years, the economy of medical tourism has burgeoned, exploiting the high optimism that surrounds biomedical technologies, in particular, stem cell treatments (SCTs). The practice is for the most part illegal or unavailable in the United States, but the proliferation of stem cell clinics in countries such as India, Thailand, China, Mexico, and Germany, and their subsequent online marketing efforts has attracted medical tourists like Joe Woolfolk, among others.

“Stem cell tourism” refers to the online, direct-to-consumer advertised industry wherein patients travel to receive unproven stem-cell-based interventions. It is impossible to accurately calculate the number of patients, like Woolfolk, who have received an unproven stem cell intervention, however, many suspect this number to be in the tens of thousands or more. Despite criticism from the scientific community, government regulators, and professional organizations, the industry continues to thrive. Providers advertise to patients by underplaying risks, peddling hope, and attempting to stifle

warnings. In addition to the problem of financial exploitation (Woolfolk spent nearly $100,000 on his first treatment) the provision of unproven interventions has been associated with causing tremors, tumors, lesions, and death. Indeed, not all participating patients have been as fortunate as Woolfolk. The current lack of clinical evidence to support stem cell therapy puts patients at risk of receiving at best ineffective, and at worst unsafe or even harmful treatments, predicating the need for increased physician awareness and patient education about these dangers.

The recent growth of stem cell tourism reflects the high optimism that currently surrounds stem cell science - a field characterized by competing conceptions of truth and trustworthiness, with patients left largely on their own in a mostly unregulated market to navigate treatment options. While optimism surrounds many, if not most, biotechnologies, this seems to be especially high with SCTs, given the strong 'translational ethos' that surrounds this field.[1] Indeed, stem cell research is 'a poster child for translational research' in that it embodies the dominant ethos that research will produce concrete outcomes. Scientists are required to promise specific results up front in their research grant applications and 'must produce results sooner rather than later and more specifically targeted for particular ends rather than for general good.' Public investors provide much guidance in this respect. Governments in Australia, the US, the UK, and elsewhere have invested hundreds of millions of dollars in the expectation that the findings from stem cell research will be translated into marketable treatments in the not-too-distant future. The market for stem cells is already sizeable and rapidly growing - from $26 billion in 2011 to a projected $119 billion in 2018.[2]

Widely promoted for their regenerative prospects, SCTs are seen to have considerable potential for treating the degenerative diseases and disabilities associated with rapidly aging populations. Breakthroughs in stem cell science are predicted to underpin the growth of regenerative medicine in the future.[3] Internationally, many clinical trials involving stem cells are underway - 1700 studies were recruiting in July 2013.[4] However, most are at the very early stages of translation, focused on safety with low intake numbers. Consequently, such trials are not readily accessible by those who would like to participate in a regulated study. In this context of high, yet unfulfilled expectations, many clinicians fear that desperate patients may submit themselves to clinically unproven SCTs and suffer harm and financial exploitation.

Some debates about curbing unapproved SCTs focus on tightening regulations, however, while it may take years for policy to catch up with this burgeoning industry, more emphasis should be placed on arming patients with information to discourage them from crossing borders to pursue fraudulent and potentially dangerous stem cell

---

[1] Maienschein, J, et al. (2008) The ethos and ethics of translational research, *American Journal of Bioethics,* 8, 3, 43-51.

[2] Transparency Market Research (2013) *New Stem Cells Market Research Report Published by Transparency Market Research, PR Web.* Available at http://www.prweb.com/releases/2013/7/prweb10960023.htm

[3] National Institutes of Health (2001) *Stem Cells, Scientific Progress and Future Research Directions.* Washington, DC: Department of Human Services and Health.

[4] ClinicalTrials.gov (2013) ClinicalTrials.gov. A Service of the NIH. http://clinical-trials.gov

treatments. Managing patients' therapeutic hope - in addition to tighter regulation of commercial therapies and improved patient understanding - may offer a more comprehensive approach to reducing the overall incidence of stem cell tourism. Such patient support must occur early in the clinical relationship after appropriate assessment and discussion. In the psychological literature, hope is understood as having a dynamic "architecture" composed of (1) goal-directedness; (2) pathway thoughts concerning how to achieve one's goals; and (3) the perceptions that one has the ability to pursue these pathways.[5] If a patient is motivated by therapeutic hope to pursue a commercial stem cell therapy, it is likely that this motivation will have the following structure: (1) the patient has the goal of disease amelioration; (2) the patient believes stem cell therapy is a pathway to this goal; and (3) the patient believes he or she is capable of pursuing this pathway by traveling to a stem cell clinic. Better patient education may cause a patient to reevaluate whether a proffered stem cell therapy is likely to serve as a pathway to his or her goal.

A clinical regenerative medicine consult service designed to guide, counsel and inform patients on treatment options, both domestic and abroad, may be just the thing required to fill the current educational gap between the flourishing regenerative medicine industry and the patient consumer. Such a service could provide the missing elements for informed decision-making by illustrating differences between established stem cell therapies, legitimate clinical research, and unproven therapies; describing hallmarks of clinics offering unproven interventions (e.g., using one type of stem cell to treat many diseases); explaining risks associated with unproven stem cell interventions; explaining different kinds of evidence and why some, i.e., patient testimonials, should not be given much weight; and providing a description of the clinical translation process and the need for proper ethics and regulatory oversight to ensure safety and efficacy.

Furthermore, research shows that most patients seeking unapproved SCTs abroad have very little knowledge on the details of their treatment. In a number of cases, individuals claimed to be injected with cells from their own body; in other cases, where the cells used were not their own, they sometimes mentioned that they were aware of the sources of stem cells or the manner of their handling prior to their treatment. However, in these and other cases, the participants made no references to the origin of the allogeneic cells used in treatment, how they were stored, whether cells were obtained after informed consent and the ethnicity of the original cell donor. Nor did they raise significant concerns about the potential transmission of infections and whether the cells had been fully screened. While the method of delivery was not consistent for all patients, many reported they had received the cells via intramuscular or intravenous injections. Cellular transplants are not without physical risks, with one study showing that complications, including meningitis, occurred among patients with spinal cord injury following transplantation of fetal brain tissue at a clinic in China.[6] There have also been

---

[5] Snyder, C.R. (2000) Hypothesis: there is hope. In Handbook of Hope: Theory, Measures, and Applications, CR Snyder, ed. San Diego Academies Press, pp 3-21.

[6] Dobkin, BH, et al. (2006) Cellular transplants in China: observational study from the largest human experiment in chronic spinal cord injury, *Neurorehabilitation Neural Repair,* 20, 1, 5-13.

recent reports of patients developing lesions and tumors[7] and at least two reported deaths following SCTs.[8][9]

Research shows that the public increasingly turns to the Internet for information about science and health.[10] In addition to information about SCTs, patients may also seek general information about stem cell biology, clinical translation of stem cells, and ethical issues. Educating patients, while valuable in its own right, may or may not ultimately alter the demand for unproven SCTs. Evidence and expert advice are only one of many factors that influence decisions about these services. As noted by Alan Petersen, the educational "approach is underpinned by a rational actor model that assumes that individuals will rationally weigh up options in light of available information before deciding on the optimal decision. It overlooks the context in which identity is formed and hope assumes meaning."[11] Still, educating patients will help them make more informed healthcare decisions irrespective of whether education is effective at dissuading patients from seeking unproven interventions. Although the issue about whether education changes the minds of patients to seek unproven SCTs remains empirically unassessed, patient information may be helpful at correcting some misinformation (i.e., debunking claims that SCTs are risk-free). While currently the unproven market for SCTs can be clearly distinguished, this separation may become increasingly obscure as more stem cell research enters clinical phases. Consequently, the blurring between unapproved but legitimate clinical research and more questionable unproven interventions will make it increasingly difficult for patients to navigate the clinical stem cell landscape - thus, underscoring the great need for better infrastructure and services able to effectively guide patients. Thus, one of the goals of such a service would be to help clarify concepts, explain how research leads to products, and help patients discern between legitimate research and fraudulent therapies. Arming patients with the right information is valuable irrespective of the decisions they ultimately make on whether to undergo an unproven stem cell intervention. Services like a regenerative medicine consult service may be invaluable at providing the necessary information to both clinicians seeking to guide patients as well as patients pursuing inquiries and interest in receiving SCTs.

Stem cell tourism is both a threat and an opportunity – better to seize the opportunity and act positively rather than just condone the practice without offering pragmatic solutions for the best way forward.

---

[7] Amariglio, N, et al. (2009) Donor-derived brain tumor following neural stem cell transplantation in an Ataxia Telangiectasia patient, *PLoS Medicine,* 6, 2, 221-30.

[8] Mendick, R and Hall, A. (2011) Europe's largest stem cell clinic shut down after death of baby, *The Telegraph,* 8 May.

[9] Pepper, J (2012) Croydon man died in long haul op, inquest hears, *The Croydon Guardian,* 26 January.

[10] Pew Research Center's Internet & American Life Project, 2011.

[11] Petersen, A., Seear, K., and Munsie, M. (2013). Sociol. Health Illn. http://dx.doi.org/10.1111/ 1467-9566.12092.