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The Case for Stem Cell Counselors

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In little more than a decade, stem cell science has moved rapidly from discovery to testing in the clinic. Hundreds of stem cell clinical trials are estimated to be underway for a wide range of conditions (Trounson et al., 2011, 2012). A 2013 Pharmaceutical Research and Manufacturers of America report lists nearly 80 industry-sponsored cell trials under Food and Drug Administration review; 48 are classified as stem cell trials, and 5 of these are in phase 3 (Pharmaceutical Research and Manufacturers of America 2013). In cardiovascular indications alone, over 100 studies claiming stem cells as a modality are underway (National Institutes of Health, 2014). Dozens of these cardiac trials have already been completed (Zhang et al., 2014).

This robust translational push equates to thousands of patients enrolled in stem cell trials, and many more thousands of prospective participants inquiring about whether they are eligible for new studies. As a result, Trounson et al. (2012) warn that there is an urgent need for professionally trained staff to objectively explain the risks and benefits of stem cell transplants to prospective clinical trial subjects and their families. These trained experts, described here as stem cell counselors, could help potential participants navigate among trials; explain risks, benefits, and therapeutic alternatives; and provide information about unproven transplants offered outside the bounds of clinical research. Stem cell counselors would also work closely with patients enrolled in clinical trials and serve as a public resource for patient education and outreach efforts.

This paper describes how a new counseling profession could support clinical sites and patients enrolling in stem cell clinical trials. A model is proposed, along with a curriculum that would provide counselors with the tools to address major issues facing the clinical stem cell field. Finally, a candidate recruitment and clinical site interface scheme is offered.

The Model: Genetic Counseling

Genetic counseling—which emerged out of advances in human genetics—is a mature and successful example of a client-centered approach to medical care. At its core, genetic counseling provides information and support for people who have or may be at risk for genetic disorders. While genetic counseling began in pediatric/medical genetics and prenatal diagnosis, these professionals now work in many specialty areas, including assisted reproductive technologies, noninvasive prenatal testing, cancer, cord blood banking, cardiology, neurology, psychiatry, metabolic disease, and genomics/personalized medicine (Minkoff and Berkowitz, 2014; Hendrick and Cobos, 2010). While these subfields are guided by genetics and heritability, a principle that finds resonance here is the acknowledgment that counseling is a communication process with patient autonomy at its core. Other long-standing precepts include knowledge of science, patient advocacy, respect for the values of patients and families, and teaching and providing information at a level appropriate to the patient's understanding and interest. Collectively, these activities serve to encourage context-rich, informed patient decisions (National Society of Genetic Counselors, 2014). The National Society of Genetic Counselors has recognized the importance of stem cell trials in a recent position statement outlining the different roles that genetic counselors can play in stem cell research, including identifying appropriate research subjects and educating the public (Kirkpatrick et al., 2013). However, counselors with rigorous training in stem cell sciences and related ethics, law, and social implications (ELSI) disciplines would provide the greatest benefit for patients and the public.

There are several models of genetic counseling that could ably serve patients seeking stem cell transplants. In light of the misinformation and hype surrounding stem cell science, a teaching-based, information-centered method would seem to have clear advantages. However, a strict patient education model may fall short when considering the ethical, social, and political complexities of stem cell clinical trials. Instead, a nondirective, person-centered model—developed by the psychologist Carl Rogers in the 1950s—would value the patient's belief system, strive to understand the patient's experiences a larger social context, and empower the patient to make independent, informed definitions free from coercion (Veatch, 2003). Taking this nondirective approach one step further, a biopsychosocial model—first proposed by George Engel—would attend to the biological, psychological, and social dimensions of the illness. Adapted to stem cell trials, this approach would integrate objective biomedical data along with the patient's subjective experience. In Engel's scheme, the goal is to transform the patient's role from a passive recipient of information to one of active, informed choice

supported by a caring, empathetic relationship (Engel, 1977; Borrell-Carrió et al., 2004).

With these genetic counseling models in mind, stem cell counselors would offer important advantages to individuals seeking to enroll in trials and assistance to study personnel. They include communicating specialized patient information, guarding against stem cell tourism, and bolstering the process of informed consent and personal autonomy.

Communicating Specialized Patient Information

Stem cell research organizations such as the International Society for Stem Cell Research (ISSCR), the Stem Cell Network of Canada, and the Australian Stem Cell Centre have produced educational materials on websites to help patients understand clinical trials, assess scientific evidence, and identify possible rogue clinics (International Society for Stem Cell Research, 2014; Stem Cell Network of Canada, 2014; National Stem Cell Foundation of Australia, 2013). These materials also highlight existing clinical trials and successful research outcomes (Master and Ogbogu, 2012), but traditional types of patient outreach and education efforts suffer from three limitations. First, the information is often transmitted one way—from experts to patient—without knowing whether it has been effectively communicated or whether it accounts for what patients and families might find most valuable in their decision making. Outreach is most effective when it directly engages individuals and respects values-based opinions and has become an essential part of patient-centered outcomes research (Patient-Centered Outcome Research Institute, 2014; Lensch, 2011; Murdoch and Scott, 2010). In addition, these materials encourage patients to consult with their physicians for specific information about preclinical studies, ethical oversight, and possible treatments. Professional responsibilities and legal obligations dictate that physicians must help patients understand this information, yet some physicians may not have the needed expertise—or the time—to offer meaningful recommendations, especially for those unproven stem cell interventions offered outside the bounds of a clinical trial (Levine and Wolf, 2012; Zarzeczny and Caulfield, 2010). Second, in a fast-moving, fluid field, patient education materials can quickly become outdated. Information may not reflect the most recent clinical or preclinical evidence supporting a study or fully detail the risks and benefits associated with a specialized type of transplant. Finally, materials are often generalized for broad audiences. Here, training in bioethics, regulation, and social implications of stem cell research would enrich communications with a wide variety of patients. Research subjects may have deeply held moral views or have widely varying degrees of technical and scientific understanding. They may need an advocate to help them interpret results, navigate the hospital system, and ensure proper follow-up care. For example, some trials, such as for autism or spinal cord injury, may be conducted in charged and complicated sociopolitical environments. Some patient populations will be more vulnerable than others, and some may have different impressions of risk and benefit (Liu and Scott, 2014; Scott and Magnus, 2014). Finally, the local context of clinical trials is critical to meet local expectations, as fundamentally different types of relationships exist between patients and researchers (Hunt et al., 2005). As specific types of cells are used to treat specific diseases, counseling information will have to be current, accurate, and personalized.

Guarding Against Stem Cell "Tourism"

As the advent of genetic counseling served to distance human genetics from eugenics, an argument can be made for drawing a sharp boundary between ethical and unethical clinical practice in regenerative medicine (Veatch, 2003). Chief among these is the practice of traveling to receive unproven stem cell interventions, often called stem cell tourism (the common use of the term "stem cell tourism" is not generally preferred, although it continues to be widely used in the literature). This is primarily an Internet-based, direct-to-consumer marketed industry where patients travel to destinations outside their home country to receive untested and unproven clinical stem cell injections (Master and Resnik, 2013). One of the hallmarks of stem cell tourism is a form of arbitrage, where a market of clinics and patients—representing supply and demand—are set up along permissive and restrictive regulatory gradients. As a result, clinics offering unproven treatments are drawing unprecedented numbers of patients (Trounson et al., 2012).

Seeking out unproven stem cell interventions is not limited to international destinations. To varying degrees, some transplant clinics in the United States and other jurisdictions operate outside of regulation. In the United States, patients may frequent unregulated clinics in other states or within their own state. When it comes to guarding against stem cell tourism, there is little reliable information for potential patients on how the translational process ensures the safety and efficacy of stem cell treatments (Master et al., 2013). Disease advocacy groups lack good web-based educational content about stem cell clinical translation, and even scientific organizations have little information on proven stem cell treatments, the clinical translation process, and stem cell pseudomedicine (Master et al., 2014). Without a clearinghouse for patient education, resulting harms from stem cell tourism are sweeping and troublesome, including physical risk, erosion of public trust from ineffective procedures, and failure to gain generalizable knowledge. Undue burdens on health systems can result