Survey details stem cell clinics ahead of regulatory approval

A growing number of clinics offer unproven and possibly unsafe stem cell treatments to patients who are willing to travel thousands of miles in pursuit of a cure. To help people make more informed decisions, an international society of stem cell clinicians has published a preliminary survey of centers. But some experts say the survey rates some therapies that have not yet been approved and may ultimately mislead desperate consumers.

The International Cellular Medicine Society (ICMS), a nonprofit group that claims a membership of 224 physicians and researchers from 21 countries, unveiled a survey in April offering details about 22 clinics that offer adult stem cell therapies. The survey is based on the clinics' voluntary responses to a series of questions about the sophistication of their protocols. Although the ICMS, formerly known as the American Stem Cell Therapy Association, is headquartered in Oregon, the report focused on stem cell clinics based outside the US.

Medical professionals from the ICMS judged the complexity of the clinics' cell processing and implantation techniques and graded each on a scale of one to three. "The concept was to compare the cost versus the complexity," says ICMS medical director and cofounder Christopher Centeno. "The intent was not to evaluate other aspects of value, such as outcome versus cost."

The 22 clinics on the list purport to treat more than 70 ailments ranging from diabetes to Parkinson's disease and span the globe from Ukraine to El Salvador. A total of nearly 200 companies advertise services involving unproven uses of stem cells online, according to Douglas Sipp, who studies stem cell policy and ethics at the RIKEN Center for Developmental Biology in Kobe, Japan.

"The most important thing is to put the information out there so that patients and clinicians can look at it and make their own conclusions," says ICMS executive director David Audley.

"We're not making recommendations on any one of these clinics," Audley adds. "This is just the data that you as a consumer or a clinician need to look at."

In addition, the ICMS established a treatment registry, currently with six of the 22 listed clinics signed up, to track the health of people who undergo stem cell therapies for up to 20 years after treatment. This service—which aims to provide independent oversight—is supported by the patients, who each pay a flat fee of $350 in addition to the cost of treatment. Opting out is not an option for patients at registered clinics. The fee provides the bulk of the ICMS's funding.

The organization is also launching a certified treatment registry for clinics that have been fully accredited by the ICMS. Currently, only Centeno's clinic outside of Denver has received accreditation. The ICMS plans to include US-based clinics in its next survey.

Listed efforts

Independently, the International Society for Stem Cell Research (ISSCR), which counts more than 3,000 members, last year launched a task force charged with creating a listing of asserted stem cell therapies that are unsupported by published scientific evidence. But patient groups say they want more information about working clinics.

"We need something right now, and we need practical advice, and this is what the ICMS is providing," says Barbara Hanson, cofounder of Stem Cell Pioneers, an online patient-moderated forum for discussing stem cell therapies.

But Bernard Siegel, executive director of the Florida-based nonprofit group Genetics Policy Institute, says the ISSCR remains the best go-to source for authoritative information, and he urges would-be stem cell tourists to "carefully use due diligence, not only researching the clinics, but the organizations purporting to survey and grade the clinics."

Regulation remains the major sticking point between the two societies. In agreement with the US Food and Drug Administration (FDA), the ISSCR views adult stem cells as biological drugs, whereas the ICMS sees transplanting a patient's own stem cells as a medical procedure.

"The [FDA] seems to be confused with what is the practice of medicine and what's biological drug production," says Centeno.

Centeno, a pain management physician, reported in March that he injected more than 200 people with their own cultured bone marrow stem cells to treat joint problems and saw no tumors form at the reimplantation site (*Curr. Stem Cell Res. Ther.* **5**, 81–93, 2010).

Pros and cons

The ICMS survey is being met with a mixed response from the stem cell community. Ralph Dittman, a former surgeon and professor at Baylor College of Medicine in Houston welcomes the plurality of opinions. "The more information, the merrier," he says. "It doesn't hurt to get these other views if the consumer is smart enough to discern what's fact and what's fiction."

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Dishing on clinics: Stem cell therapies weighed.

But Walter Gardner, chief of the consumer affairs branch of the FDA's Center for Biologics Evaluation and Research, maintains that most adult stem cell therapies offered both in the US and elsewhere violate the FDA's requirement that human cells are minimally processed and are used for the same basic function in both the donor and the recipient, even if those are the same person. "Many stem cell therapies are not intended for a homologous use and are more than minimally manipulated," he says.

Sipp also worries that ICMS members might be putting their own financial interests ahead of those of patients by promoting some unproven treatments. "There's a real risk that the ICMS is trying to deregulate all of autologous stem cell applications regardless of what the use is going to be," he says.

The ISSCR task force, which counts Sipp as one of its members, plans to ask stem cell clinics to provide peer-reviewed evidence of efficacy and safety in animal studies and clinical trials, as well as to demonstrate government and institutional review board approval ahead of commercialization.

That's a high bench mark, says ISSCR president-elect Elaine Fuchs of Rockefeller University in New York—but one that is necessary to protect vulnerable patients, she stresses. "We want to make it clear that many of the therapies that are reported as being fabulous cures for many different types of disease are still in their infancy and not backed up by the scientific evidence," she says.

Elie Dolgin, New York