



amednews.com
American Medical News

STAY INFORMED

- E-mail Alerts
- RSS
- XM Radio
- Mobile Edition

PROFESSION

Guidelines target stem cell medical tourism

Some clinics are taking advantage of desperate patients, says an international group of stem cell scientists.

By [Kevin B. O'Reilly](#), AMNews staff. Posted Feb. 2, 2009.

Growing numbers of clinics abroad are marketing unproven, costly stem cell therapies to medical tourists and "exploiting patients' hopes," according to a report from the International Society for Stem Cell Research.

The Deerfield, Ill.-based group convened a task force of researchers, ethicists, doctors and regulatory officials from 13 countries to devise guidelines that target clinics offering experimental therapy to patients without appropriate transparency, oversight or patient protections.

- [Stem cell boundaries](#)
- [Links](#)
- See [related content](#)
- [E-mail](#) - [Print](#) - [Write a letter](#)

"There is this tension between the slow progress of medical science and the desperation of patients and the swiftness with which disease overtakes them," said Laurie Zoloth, PhD, on the task force that issued the report in December 2008.

"Combine that with a flat world and the Internet, and it's a

recipe for stem cell fakery."

Restrictions on federal funding for embryonic stem cell research have contributed to the trend, said Zoloth, director of the Northwestern University Feinberg School of Medicine Center for Bioethics, Science and Society.

"Americans could be lured into other countries because of their recognition that stem cell research might be held back here," Zoloth said.

The average cost for stem cell treatment overseas is \$21,500.

The number of patients who have traveled abroad for stem cell therapies is unknown, though experts said that anecdotally it appears to be in the thousands. That represents a sliver of the 750,000 Americans who left the U.S. for medical care last year, according to the Deloitte Center for Health Solutions.

Josef Woodman, author of the medical tourism guidebook *Patients Beyond Borders*, said he has yet to come across a patient traveling abroad for stem cell therapy but said he would advise patients to steer clear. "It's unproven and experimental," he said. "There are plenty enough challenges with medical travel as it is."

The proliferation of clinics marketing purportedly effective stem cell interventions online has many experts worried. A December 2008 study of stem cell clinics' Web sites found that they claimed to treat a range of diseases that go beyond the scope of the early evidence on stem cells' efficacy, while playing up the benefits and talking little about risks. The study, published in the journal *Cell Stem Cell*, found that the average price tag for the treatments, excluding travel and lodging costs, was \$21,500.

"We're not presuming they're all quacks. Maybe they genuinely believe in what they're doing," said Timothy Caulfield, a study author and the Canada Research Chair of Health Law and Policy at the University of Alberta. "But if the stuff really works, let's see the data. They need

to be as transparent as possible. We need more than just testimonials."

The American Medical Association in July 2008 adopted principles on medical tourism, calling for patient choice, informed consent and continuity of care. In 2003, the AMA adopted policy supporting "federal funding for research involving human pluripotent stem cells."

Setting ideal standards

Insoo Hyun, PhD, who helped lead the ISSCR task force, said, "It looks like there are a lot of snake oil clinics popping up, but it was really hard to pin down exactly what was morally wrong about these clinics."

Hyun, associate professor of bioethics at Case Western Reserve University School of Medicine in Ohio, noted that costly procedures, medical tourism and innovation outside the clinical-trial context are not necessarily verboten. "Instead of trying to chase the stem cell clinics directly, we decided to imagine the best-case scenario. Then, looking at the ideal standards, we would have the lens to go back and look at the clinics and see where they were deficient."

750,000 Americans traveled outside the U.S. for medical care in 2008.

The best-practice guidelines for what the task force calls "stem-cell based medical innovation" call for better transparency, oversight, informed consent, patient follow-up and a clinical trial after experience "with at most a few patients." Hyun said the proposed road rules stand in stark contrast with stem cell clinics that claim success with hundreds of patients yet never publish results in peer-reviewed journals.

The hope is that the task force guidelines will give regulators the backing they need to take action against unscrupulous operators, said George Q. Daley, MD, PhD, immediate past president of the ISSCR and associate director of the stem cell program at Children's Hospital Boston.

"Regulators have a responsibility to prevent exploitation of patients in their jurisdictions, and where necessary, to close fraudulent clinics and take disciplinary action against the doctors involved," Dr. Daley said.

Some experts said the new guidelines went too far in allowing experimentation in a small number of patients outside clinical trials.

"We have very little data about what works and what doesn't, and which [stem cell therapies] are harmful or potentially harmful, or toxic, or cause rejection problems," said Summer Johnson, PhD, executive managing editor of *The American Journal of Bioethics*. "The justice argument for why people should be allowed to pursue whatever therapy they want -- I feel at this stage in stem cell therapy development, it's premature."

The ISSCR guidelines call for "fair access" to stem cell innovations for the poor and those in developing countries. The group released a guide for patients, available online (www.isscr.org/clinical_trans).

The print version of this content appeared in the [Feb. 9, 2009](#) issue of *American Medical News*.

[Back to top.](#)

ADDITIONAL INFORMATION:

Stem cell boundaries

Clinics in China and elsewhere are drawing medical tourists lured by the promise of stem cell cures. New professional guidelines say clinics providing unproven stem cell-based therapies must have:

- A written plan for the procedure that includes the scientific rationale and any preclinical

evidence of proof of principle for efficacy and safety.

- A full characterization of the types of cells being transplanted and how they will be administered.
- Clinical and administrative leadership support for the clinical experiment.
- Voluntary informed consent for patients.
- An action plan for adverse events.
- Insurance coverage or other financial resources to cover complications.
- Systematic and objective tracking of outcomes submitted to the scientific community for critical review.
- A timely move to a formal clinical trial after experience with a very small number of patients.

Source: Guidelines for the Clinical Translation of Stem Cells, International Society for Stem Cell Research, Dec. 3, 2008 (www.isscr.org/clinical_trans)

[Back to top.](#)

Weblink

"Guidelines for the Clinical Translation of Stem Cells," International Society for Stem Cell Research, December 2008 (www.isscr.org/clinical_trans)

"Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine," abstract, *Cell Stem Cell*, December 2008 ([www.cell.com/cell-stem-cell/abstract/S1934-5909\(08\)00573-0](http://www.cell.com/cell-stem-cell/abstract/S1934-5909(08)00573-0))

[Back to top.](#)

Copyright 2009 American Medical Association. All rights reserved.

RELATED CONTENT

- » **Elections seen as turning point for stem cell studies** Oct. 20, 2008
 - » **Trade group's "accreditation" could confuse medical tourists** Oct. 6, 2008
 - » **AMA meeting: Guidelines target safety of medical tourists** July 7, 2008
 - » **Travel reservations: Push for offshore care** Nov. 5, 2007
 - » **Stem cell breakthrough uses skin cells rather than embryos** Dec. 10, 2007
-