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End 'stem cell tourism', paper says

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The continued marketing and use of experimental stem cell-based interventions inside and outside the United States is problematic and unsustainable, according to a new paper by science policy and bioethics experts at Rice University's Baker Institute for Public Policy and Wake Forest University. Disillusioned patients, tired of waiting for the cures they were promised, are seeking unproven stem cell-based treatments that are causing more harm than good, said the experts, who argue that public policy is needed to reduce this form of "stem cell tourism."

The paper, "Unproven Stem Cell-based Interventions and Achieving a Compromise Policy Among the Multiple Stakeholders," was co-authored by Kirstin Matthews, a lecturer in natural sciences at Rice and fellow in

science and technology policy at the Baker Institute, and Ana Iltis, a professor of philosophy and director of Wake Forest's Center for Bioethics, Health and Society. It was published online in the journal *BMC Medical Ethics*.

"The current landscape of stem cell tourism should prompt a re-evaluation of current approaches to study cell-based interventions with respect to the design, initiation and conduct of U.S. clinical trials," the authors wrote. "Stakeholders, including scientists, clinicians, regulators and patient advocates, need to work together to find a compromise to keep patients in the U.S. and within the clinical-trial process."

The rise in stem cell tourism is a recent phenomenon, according to the paper. Scientists have long envisioned their stem cell research would lead to cures in the near future. In 2004, patient-advocate groups were major players in helping pass and implement significant public policy and funding initiatives in stem cells and regenerative medicine. In the following years, advocates were also actively engaged in Washington, D.C, encouraging policymakers to broaden embryonic stem cell research funding, which was ultimately passed after President Barack Obama came into office. After waiting more than 10 years, many of these same patients are now approaching clinics around the world that are offering experimental stem cell-based interventions instead of waiting for scientists in the U.S. to complete clinical trials.

Central problems of stem cell tourism include the lack of patient protection, U.S. liability standards, regulation of clinical sites and clinician licensing, the authors said. "These interventions have insufficient evidence of safety and efficacy; patients may be wasting money and time, and they may be forgoing other opportunities for an intervention that has not been shown to be safe and effective," they wrote. "Current practices do not contribute to scientific progress because the data from the procedures are unsuitable for follow-up research to

measure outcomes. In addition, there is no assurance for patients that they are receiving the interventions promised or of what dosage they are receiving. Furthermore, there is inconsistent or nonexistent follow-up care."

Using HIV, AIDS and breast cancer advocate cases as examples, Matthews and Iltis identified key priorities and goals for a policy effort to combat stem cell tourism.

"Policy should be aimed at bringing patients home and fostering responsible scientific research as well as access for patients," they wrote. "This will require discussions about alternative approaches to the design and conduct of clinical trials as well as to how interventions are approved by the Food and Drug Administration."

More information: *BMC Medical Ethics*, www.biomedcentral.com/1472-6939/16/75

Provided by Rice University