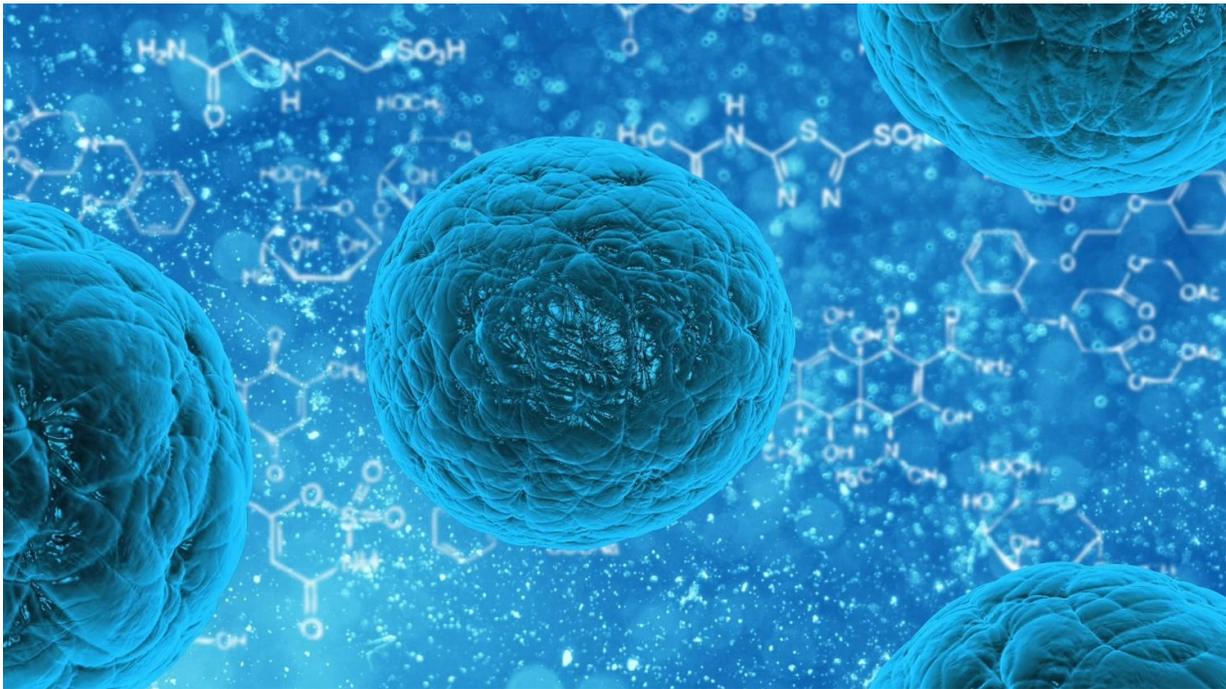


A call for global oversight of unproven stem cell therapies

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The promotion and marketing of unproven stem cell therapies is a global problem that needs a global solution, say experts in a perspective published June 8 in the journal *Stem Cell Reports*. The authors of the paper call for the World Health Organization (WHO) to establish an advisory committee on regenerative medicine to tackle this issue and provide guidance for countries around the world.

"The field of [regenerative medicine](#), which entails the manipulation of cells and tissues to obtain therapeutic properties, has been hailed as the most promising [research field](#) in [modern medicine](#)," says senior author Mohamed Abou-el-Enein, the executive director of the joint University of Southern California/Children's Hospital of Los Angeles Cell Therapy Program. "Starting in the early 2000s, however, unregulated stem cell clinics offering untested and poorly characterized treatments with insufficient information on their safety and efficacy began emerging all over the world, taking advantage of the media hype around stem cells and patients' hope and desperation."

"Advancing regenerative medicine is key to addressing the chronic disease burden, which the WHO considers to be a top international priority," says first author Zubin Master, an associate professor of biomedical ethics at the Mayo Clinic. "And even though we have had significant advancement in the field of regenerative medicine, more needs to be done to ensure the safe and timely delivery of evidence-based interventions to patients, many of whom have exhausted all available options."

The three authors of the commentary are Lawrence Goldstein Science Policy Fellows for the International Society for Stem Cell Research (ISSCR) and ex-officio members of ISSCR's Public Policy Committee. They decided to write it after realizing that the majority of efforts in this space have focused on the marketing practices of providers and clinics, with much less focus on the tightening of regulations and enforcement to deal with the issue from a global standpoint.

The commentary highlights several proposals, including the harmonization of regulatory definitions surrounding stem cell and regenerative medicine and the importance of balancing the scientific evidence demonstrating safety and efficacy of stem cell and regenerative products with the needs of the patient.

"Many patients with chronic diseases who desire a regenerative medicine option have exhausted conventional medicine treatments and have no other suitable option," Master says. "We should aim to develop pathways to provide patients with evidenced-based experimental regenerative intervention as possible options where there is oversight, especially in circumstances where there is no suitable alternative left."

The authors write that the WHO, which already has established an expert advisory committee to develop global standards for governance and oversight of human genome editing, could initiate a similar committee to address the spread of unproven stem cell treatments. They say that the committee could promote greater harmonization among regulatory standards, convince member nations to prioritize this issue on their public health agendas, and develop educational and outreach tools that could help increase awareness among physicians and patients on the danger of this practice.

"I believe that the global spread of unproven stem cell therapies reflects critical gaps in the international system for responding to health crises, which could put the life of thousands of patients in danger," Abou-el-Enein says. "Urgent measures are needed to enhance the global regulatory capacity to detect and respond to this eminent crisis rapidly."

The authors also propose the establishment of an active surveillance mechanism to collect and analyze information on dubious clinics performing these procedures and share it with the public to increase awareness, as well as taking the appropriate legal actions. They note the importance of educational programs for patients and physicians on the realistic potential of stem [cells](#) and the regulatory pathways that are in place for developing these promising therapies.

More information: *Stem Cell Reports*, Master et al.: "Unproven stem cell interventions: A global public health problem requiring global

deliberation," www.cell.com/stem-cell-reports ...
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