Regulators must step up stem cell oversight

A growing number of clinics are offering cell therapies that remain untested in rigorous clinical trials. Although the scientific community has chided the use of unproven treatments, we need less talk and more action in regulating stem cell therapies.

Scientists, clinicians and bioethicists have voiced increasing concern about the dangers of stem cell tourism in recent years. We've all heard about profit-hungry medical hucksters who exploit desperate patients with promises of unproven and potentially harmful procedures. Yet stem cell clinics that offer such unregulated treatments for everything from spinal injury to Parkinson's disease continue to flourish around the world.

In response, many of the major stem cell organizations, including the International Society for Stem Cell Research (ISSCR) and the Australian Stem Cell Centre, have issued guidelines warning patients away from clinics operating outside the medical mainstream and advising patients about what questions to ask prospective practitioners (*Cell Stem Cell* **3**, 607–609, 2008; go.nature.com/qA8CNM). But these handbooks fall short of evaluating individual treatments or clinics or calling on regulatory agencies to crack their whips.

This has created an enormous information vacuum that is now being filled by messaging and spin from the proponents of such treatments, who forge ahead with various adult stem cell therapies despite the lack of clinical trial data or regulatory oversight. On page 495, we highlight a survey conducted by one such group of clinicians, the International Cellular Medicine Society (ICMS), which last month issued its own document comparing stem cell clinics across the globe. As the ICMS leaders admit, the goal of this report was to compare price with procedural sophistication—not to evaluate the safety or efficacy of purported treatments. Although the survey does not explicitly endorse any of the clinics, it does not condemn any either. The ICMS maintains that it is providing unbiased information, but the report could be misconstrued as granting the illusion of legitimacy to the listed treatments.

To set the record straight, other stem cell organizations, including the ISSCR, need to ramp up their educational efforts. Although the ISSCR last year established a task force on available but unproven treatments, that group has yet to issue any policy statements. And, when it does, the task force will create only a blacklist of purported treatments, not of clinics, according to a society spokesperson.

But education can only go so far. Clearly, more stringent oversight is needed in the countries where these clinics are operating—both in the US and abroad. Take, for example, the Centeno-Schultz clinic near Denver, which treats people with joint problems by injecting a purified and expanded set of a patient's own bone marrow stem cells into the site of injury. This technique has not been tested in double-blinded clinical trials—the gold standard of medical treatments—nor has it been approved by any third-party regulator.

Two years ago, the US Food and Drug Administration (FDA) issued a letter charging that the clinic's stem cells counted as biologic drugs—because the cells are more than minimally manipulated, unlike standard bone marrow transplantation—and thus fall under the FDA's jurisdiction. However, the head of the clinic, Christopher Schultz, who also serves as medical director of the ICMS, maintains that he is practicing medicine in a single state, so federal oversight isn't required.

Schultz likens his clinic to an assisted fertility clinic, which also handles a patient's own stem cells—unfertilized eggs—*ex vivo* before reimplanting them after fertilization. So he feels confident that he can continue to treat patients without a biologics license application or an investigational new drug application. To his credit, Schultz has even started publishing data in peer-reviewed scientific literature (*Curr. Stem Cell Res. Ther.* **5**, 81–93, 2010). The FDA, meanwhile, remains silent.

Clear directions from the FDA are needed about whether such treatments involving cultured adult stem cells qualify as medical procedures or as biologic drugs. If the FDA says it's the latter, as the agency maintains in the case of the Centeno-Schultz clinic, then such treatments must go through the proper certification and approval processes to validate their utility and efficacy.

The time has come to take a stand against clinics that circumvent scientific and regulatory safety nets. Although federal agencies and scientific organizations must be careful not to stifle medical innovation, their top priority should be preventing harm. Stem cell clinics offering unvalidated therapies need to be singled out by name and condemned, so that when patients go searching on the Internet for last-ditch 'cures' they find an assertive and authoritative voice of caution that explicitly says 'don't go there!'. At the moment, unfortunately, the most likely Google hit remains the ICMS survey, which might sway people to choose a low price over safety and scientific evidence.