

## Nature reports on unapproved stem-cell therapies in China

April 12 2012, by Lin Edwards

(Phys.org) -- A report in the journal *Nature* on the extent of unapproved stem-cell treatments in China has found that the practice is still widespread and is attracting thousands of medical tourists to the country.

Unapproved stem-cell treatments are being offered in China for a wide range of diseases and conditions, including diabetes, Alzheimer's disease, autism, Parkinson's disease, and multiple sclerosis, and even common ailments such as tiredness or sagging skin. The numerous online advertisements clearly imply that these stem-cell therapies are an accepted and proven form of medical treatment, especially in China, where unapproved treatments are often offered by genuine medical practitioners in real medical establishments.

Apart from Chinese patients, these clinics attract thousands of foreigners each year arriving in China specifically to seek out stem-cell therapies they cannot receive in their own countries, where clinical evidence of their safety and effectiveness are required for their approval. Many are willing to pay \$63,000 or even more for a course of injections of stem-cells, which in China are usually sourced from umbilical cords or aborted fetuses.

Stem-cell therapies are promising and may have great potential for treatments, but most have not yet been proven to work, and despite a great deal of research into stem cells there is as yet little clinical evidence of their effectiveness. The clinics in China all claim the therapies are successful in treating patients, but they have not published



any data from controlled clinical trials.

Doctors and patients alike appear willing to ignore the lack of evidence in the hope that stem-cell therapies will safely provide the treatment they need. For example, Dr Zhou JingLi of Beijing Puhua International Hospital, said patients with autism show improvement after treatment. She agreed that clinical trials are needed, but said the question is who would pay for the trials, adding that the treatments are safe and effective, and the results seen in patients shows the therapies are worth doing.

However, safety and effectiveness of stem-cell treatments has not been proven, and other stem-cell experts, such as Stanford University's Ricardo Dolmetsch, are skeptical, saying that only controlled studies can provide evidence that the therapies will not lead to problems in future, such as auto-immune diseases or cancer.

Acceptance of the therapies is so widespread that <u>clinical evidence</u> is often not sought, and no systematic follow-up of treated patients is required, which means that if the treatments were to cause other problems in the future, it will be impossible to identify them as the cause. Lack of follow-up also means the clinics have no way of knowing how long any benefits lasted after treatment.

The therapies are not government-approved in China and in 2009 were classified as high risk procedures needing approval before they could be offered to patients. No approval has ever been granted, but that has not stopped the approximately 100 stem-cell clinics in China from operating.

In January this year the Ministry of Health in China tried to enforce their ban on unapproved stem-cell therapies, and instituted more stringent rules governing the industry, such as requiring companies to register their clinical and research activities and to report on their sources of



stem cells. The report in Nature shows that the ban has had little effect, with clinics still operating openly and treatments still being advertised. Few clinics have yet registered their activities as required.

There has also been concern in the US and elsewhere that some unethical organizations offering stem-cell therapies may be preying on desperate people seeking treatments for conditions that currently have few treatment options. The FDA issued a <u>warning in January</u> this year about stem-cell scams. FDA-regulated clinical trials are being carried out in the US, but few stem-cell therapies are currently approved.

**More information:** China's stem-cell rules go unheeded - *Nature* 484, 149–150 (12 April 2012) doi:10.1038/484149a

Editorial: Buyer beware - *Nature* 484, 141 (12 April 2012)

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