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CASE STUDY

# Innovative therapy or unethical experiment?

**PROGRAMME ON ETHICAL ISSUES IN INTERNATIONAL HEALTH RESEARCH**

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Over the past three years, more than 500 patients with disorders of the nervous system (ranging from Amyotrophic Lateral Sclerosis, Parkinson's disease and stroke to paraplegia and tetraplegia) have received an innovative intervention—the injection of cells from aborted foetuses into their brains and spinal cords—at a hospital in a city in southern China.

Dr W, a neurosurgeon, does this surgery. Dr W got a medical degree in China and then studied in the US before returning to practice in his country. Dr W has declined to conduct a controlled clinical trial of his method. He prefers to label it innovative therapy for those who volunteer to receive his treatment. Cell-transplant experiments have a history of several decades and continue to be pursued in several countries. What is unique about Dr W's method is the type and source of the cells that he uses, which he harvests from the noses of aborted foetuses (ideally 16 weeks old). He says all the mothers give their consent for the embryos to be used in this way and they do not receive any payment. After culling the cells to produce a sufficient volume for transplant purposes, he transplants them above and below the damaged area of the spinal cord using a hypodermic syringe. For ALS patients the cells are injected directly into the atrophied area of the frontal lobe of the brain. The cells do not replace damaged cells, Dr W says, but act as a catalyst. Dr W admits that he cannot fully explain his results but says he has seen so many improvements that there is no doubt in his mind that his method does work. His claims have been reported in the lay media as well as the medical press. He has recently submitted an article describing his success to a local journal. Many patients come from other countries to receive his treatment.

A reporter from the medical journal *The Lancet* spoke to more than a dozen former patients of Dr W, all of who said they had noticed positive change. Long-term follow-up data on Dr W's work remains sketchy. But patients contacted by e-mail several months after their operations reported continued progress, particularly those with spinal injuries. In some cases, the restoration of feeling brings pain, but Dr W claims that 70 per cent of patients experience an improvement in the quality of their lives. He says the surgery stabilises the patients' condition in about half of the cases he deals with.

He has taken video films of patients before and after surgery and has done a survey of 139 patients based on the criteria for function assessment laid down by the American Spinal Injury Association, but much of Dr W's work lacks statistical validity because he has not tested the method in a trial.

Supporters urge him to conduct double-blind trials to meet western scientific standards. Since there are no recognised treatments to reverse these conditions, the control group in a double-blind study would receive an injection of an inert fluid of the same volume as the stem cells injected or would undergo a "sham surgery" on the skull or spine. Dr W refuses, asserting that such trials and studies would be unethical. "Even if the whole world refuses to believe me, I would not do a control test," he insists. "These patients are already suffering. If we open them up just for a placebo test, it will only do them harm. We would be doing it for ourselves, not for the patient." The waiting list of foreign patients stretches until the end of next year. Enough Chinese patients have requested surgery to keep Dr W busy for ten years. He is currently training other doctors to use his technique and he occasionally lectures overseas. The difference in medical cultures has proved to be a significant obstacle he feels, in his method being accepted in the West.

## Questions

Is Dr W using innovative therapy or is he experimenting? How are these different?

Would it be unethical to conduct a placebo-controlled trial, as Dr W maintains?

How might Dr W demonstrate that this method is effective? Is there an international standard for determining efficacy?

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This case study was abstracted from: Watts Jonathan. Controversy in China. *The Lancet* 2005; 365:109-110. It was developed by the Program on Ethical Issues in International Health Research, department of population and international health, Harvard School of Public Health.