

CASE STUDY RESPONSE

Bypassing scientific requirements

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

Dr W is convinced that he is conducting innovative therapy as he has proven to himself that he is getting successful results with his treatment. He appears unconcerned about the principles of scientific research, the importance of peer review and the opinions of the community at large. To my mind, he is in the same category as our countryman Dr Dhani Ram Baruah, who carried out transplants of organs from pigs into his human patients (1).

Innovative therapy—as the name suggests—is the development of a novel technique utilising well-established principles that have stood the test of time and have gained universal acceptance. Cell transplants into the spinal cord are not standard practice, have not gained universal acceptance and are not modifications of or improvements on existing forms of treatment. Cell transplant into the spinal cord is, as the Americans would put, a completely different ball game.

Experimentation is venturing into the unknown. A hypothesis has been formulated and experiments are conducted to verify or disprove the conjecture. Experiments require scientific scrutiny, must follow guidelines that have been laid down after

much thought and, when performed on humans, must only be attempted after obtaining the sanction of a properly constituted and respected ethics committee. Dr W has bypassed all the requirements of scientific experimentation.

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

No. It is unethical NOT to conduct a placebo-controlled trial. If, in the course of such a trial, the results are unequivocally in favour of the cell transplant and are statistically proven, further trial can be discontinued in the interests of patients.

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

Neurological recovery of the patient would determine efficacy of treatment. However, in order to demonstrate efficacy, the patients must be examined by respected, independent experts of proven integrity in no way connected to the trial, followed up by these experts and assessed at the end of the trial period by these experts.

Reference

1. Vox Populi The first Indian porcine xenotransplant. *Issues Med Ethics* 1997;5 (2):62.