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CASE STUDY RESPONSES

# Therapeutic innovation or cynical exploitation?

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"*Aap mujh par experiment kyon nahin kar sak te*?" ("Why can't you experiment on me?")

MS is a young engineer from a fairly well-off Ludhiana family. A passion for fast motorcycles ended in an accident in 2001 which is when I first saw him. He had a fracture-dislocation at C6-7 which initially caused quadriplegia but eventually evolved into an anterior cord syndrome causing paraplegia. Over the next three years, hand function had improved to the point that he could manage a motorised wheelchair and perform intermittent self catheterisation. It also allowed him to obsessively surf the net for cures for his paraplegia. He came to me a year ago, after a gap of almost two years, armed with a stack of printouts on stem cell transplants. My arguments that no reputed hospital or neurosurgeon would participate in an individual experiment of this nature did not convince him and that was the last I saw of him. Two months ago his nephew came to me for a consultation and in the course of the conversation told me that his 'Chachu' was planning a trip to China. *(MS' is a composite case history)*

Most people are unaware of how medical progress really happens. Unfortunately this includes a large proportion of medical professionals as well. The media has its own agenda – selling newsprint. And hype sells more than commonsense. The fact that most research aims at incremental progress and often occurs over decades is usually forgotten in the noise over "the next big thing". Science, and medicine is a part of it, advances on a broad front. Technological advances in other fields spawn materials that can be used in medicine and require new techniques to use them. Funding depends on either large-scale public (governmental) support or an entrepreneurial mindset sustained by the ecology of the market, often both. This symbiosis is by the nature of things a messy, unpredictable patchwork. Occasional examples of successful coordinated efforts across countries and institutions such as the Human Genome Project should not obscure this basic reality.

As and when these advances eventually become therapeutically significant, ethical questions arise. Reconciling individual patient interests in the short term with a broader long-term view of public good is almost always complicated by individual (and institutional) agendas. It is usually at this point that the question of innovative treatment versus unethical experimentation arises, and it is a black vs white trap that must be avoided.

Neurological regeneration is viewed as the last frontier of medical research. Of the chronic neurological ailments, spinal cord injury (SCI) gets the most attention. This may be because, unlike Alzheimer's disease for instance, patients can vociferously advocate their own real, or perceived interests. SCI occurs at an incidence of 20-50 cases per million population and often results in permanent neurological damage and substantial disability. About 60 per cent of cases occur in the second to fourth decades and 85 per cent are male. A little over half occur in the cervical region. Current advances in treatment are focused on early diagnosis and initial management. Since many cases of SCI occur in the setting of polytrauma or are associated with head injury they may be missed by untrained personnel. Much effort has gone into making paramedical personnel aware of the problem and optimising patient handling during transfer to hospital. Early treatment with high doses of intravenous steroids has been convincingly shown to improve long-term results in many cases and it is now the standard of therapy in acute care. Long-term care, however, remains difficult and needs a team approach to rehabilitation. Complications related to the injury such as urinary infections, decubitus ulcers and deep vein thrombosis can substantially impact quality of life and cause early death. And yet prolonged survival is possible. Barely half a century ago without antibiotics paraplegia was almost a sentence of death.

The rise of the internet has spawned the growth of communities of affected individuals and their families. In the US the Christopher Reeves Foundation amongst others leads in fundraising for research on SCI. Progress however has been slow and most publications on stem cell use in SCI describe only modest results in animal models. In the US human studies have been blocked by the recent ban on the use of foetal origin stem cells. But the substantial media hype over the potential of stem cells to revolutionise treatment suggests that the Holy Grail has almost been reached.

In this scenario, it is obvious that a market for stem cell "treatment" now exists world-wide. The only question is where it can be serviced.

Stem cell research requires a fair amount of institutional expertise in cell biology. Setting up infrastructure and training personnel need substantial resources and can only be done by government-funded agencies. Another requisite is the presence of adequate hospital facilities. A willing surgeon needs to be backed up by good post-operative care and intensive care facilities. Rehabilitation programmes also have long gestation periods and are not easy to set up. Such facilities in the public

sector will have bureaucratic oversight and a pool of skeptical colleagues to stymie adventurism. So the next requirement is a large private sector hospital to provide support. In a booming economy this will be accompanied by the availability of a pool of patients able to afford "pay-as-you-go" private medical care. This too is important since insurers are unlikely to pay for this kind of treatment.

One more requirement is not so easy to divine. Patient autonomy and informed consent need to be buttressed by a functional medical regulatory environment which in turn requires support from civil society. The Indian medical regulatory environment is dysfunctional for routine purposes and can prevent egregious exercises in medical adventurism only if actively prodded, usually by the courts. In an authoritarian set-up even this check may be absent.

Put yourself in the place of a patient surfing the net for hope. A few clicks and you reach the website www.stemcellschina.com, and in turn a link to a write-up on a Prof Huang Hongyun, a practising neurosurgeon who specialises in implanting "olfactory ensheathing cells" (OECs) harvested from foetuses, into spinal cord injury, stroke, Parkinson's disease and amyotrophic lateral sclerosis. Dr Huang's site has patients describing their experiences, invariably positive. His long waiting list is mentioned, as is the cost for international patients: $20,000. His technique is fairly simple: the spinal cord is exposed above and below the site of injury and a suspension of OEC's is injected. In motor neuron disease, the cell suspension is injected into the frontal lobes. Presumably, for stroke and Parkinson's disease, the appropriate areas of the nervous system are injected.

In the case study described here, it is noted that Dr W (presumably Dr Huang) has no idea how this "works". The good doctor is quoted as being convinced that he is helping his patients, that a controlled trial would be "unethical" and that if it were not for the difference in "medical cultures" his methods would be widely accepted in the West. There is no mention of any patient with a visible and dramatic improvement in function, unexplainable by the natural course of the underlying medical condition. Since response is a bell-shaped curve, given 500 patients there should be at least 5-10 such positive outliers.

With regard to Dr Huang's claims to the shield of cultural difference, the randomised controlled trial is the only effective method of judging the efficacy of any treatment. At its most basic, a controlled trial attempts to compensate for two things: the placebo effect (which can be substantial especially if you have paid large amounts of money for a treatment) and the natural history of an illness. Most incremental advances in therapy show only a statistically significant difference in outcome between therapy and placebo. This often requires a large volume of patients to tease out and this can be a deterrent for specialised surgical procedures. But if one's peers are convinced then organising a multi-centre trial is not impossible. If a treatment has promise then even a minor but statistically significant result becomes a cue for further research, improvements in technique and so on.

However a controlled trial also runs the risk, to the innovator, of killing his baby. The external carotid-middle cerebral (EC-MC) bypass was a surgical feat that promised to revolutionise stroke therapy by pouring arterial blood into the starved cerebral vascular bed. Large numbers of cases were performed by neurosurgeons convinced they were operating for the good of their patients. Ultimately, a multi-centre controlled trial pushed through by the neurological community in the US proved that it was worthless. Much acrimonious debate followed but this innovative method for treating ischemic stroke is now dead.

The case study raises some fundamental issues. The question presented for discussion is easily answered. Dr W's treatment is, after 500 surgeries, neither innovative nor experimental. It should either be validated as a genuine medical advance via the medium of a controlled trial (preferably multi-centre, randomised and if possible, placebo controlled) or abandoned.

The more difficult issue relates to patient choice, especially when the patient can pay for his own "innovative therapy/experiment". Without an effective institutional framework for resolving ethical issues, it is the "Wild West" where anything goes. Genuine research that has a sound scientific basis and is replicable elsewhere will not raise significant concerns but anything else needs a healthy dose of skepticism.