

FROM THE PRESS

Regulation blues

The Indian Medical Association is holding country-wide protests against the union government's proposed amendments to the Medical Council of India Act, fearing that these will curb the autonomous status of the MCI. The government states that the amendments are being brought in to curb corruption in the MCI.

The government seeks power to nominate four to five members of its choice to the MCI, who may not be medical professionals. It also wishes to amend the Act to get the power to nominate members to the MCI in case there is a vacancy. So far, vacancies have been filled through a process of election. The government wants the power to remove MCI's president and vice-president by a two-thirds majority in case it deems fit.

Doctors across the country are apprehensive over the latest turn of events, which threaten to jeopardise the autonomy of the MCI. To defeat the amendments, the heads of IMA branches all over the country have written to all departments concerned in the union health ministry.

Tribune News Service. IMA opposes proposed amendments to MCI Act. September 3, 2005.

Poor patients must pay

When the All-India Institute of Medical Sciences introduced "revised hospital charges" without prior announcement, many poor patients who had travelled long distances were forced to return home without treatment. Tests that were previously free, including routine blood and biochemistry tests, ECG and blood gas level tests, now come under the "charged for" category.

A hospital directive notes that these fees do not apply to casualty patients, employees' health scheme beneficiary patients and AIIMS students. "Exemption of charges for poor patients will be allowed as per existing guidelines." AIIMS' senior financial adviser Mayank Sharma described the charges as "a marginal increase" necessitated since charges had remained stagnant for the past ten years.

"How can we allow the hospital to function as a commercial unit?" asked the vice-president of the Joint Council of Health Employees' Organisation, SS Rana.

Staff reporter. A bolt from the blue for patients at AIIMS. The Hindu, November 30, 2005.

Tracking trials

The Indian Council of Medical Research plans to establish a registry of clinical trials conducted in the country. The Drugs Controller General of India also plans to train regulators to scrutinise trials and ensure compliance with ethical guidelines and good clinical practice. This was announced at a closed conference of government officials, industry representatives, and doctors to consider India's capacity for clinical trials. The DCGI noted that there were nearly 100 multi-centre drug trials in

India. The industry estimates that India earned about \$17 million in revenue through clinical trials in 2003.

A survey by the Indian Council of Medical Research earlier in the year showed that one in two institutional ethical committees had a chairman or chairwoman from the parent institution, creating potential for a conflict of interest. Only 40 of 179 committees follow prescribed guidelines.

Ganapati Mudur. India plans to audit clinical trials. BMJ, November 5, 2005.

Stem cells – the story from Pakistan

In a letter published in *Dawn*, Pakistan, Dr Farhat Moazam, chairperson of the Centre of Biomedical Ethics and Culture, Sind Institute for Urology and Transplantation, Karachi, expressed concern at a press advertisement by a private company, Tristem, offering hospitals machines for stem cell therapy to treat thalassaemia and other diseases. "In the absence of ethical guidelines, negligible oversight processes at institutional and national levels, and lack of regulation of healthcare services, it is not difficult to imagine a proliferation of clinics and hospitals promising desperate patients treatments for all manner of illnesses by using stem cells."

Dr Moazam also notes that such advertisements contribute to the hype "generally nurtured by commercial interests" about this technology. Much work on this is in the research stage, and research in this subject must follow both scientific procedure and ethical review. There is no published literature on the use of stem cell therapy for thalassaemia.

Farhat Moazam. Stem cell therapy. Letter. Dawn, September 24, 2005.

Stem cell stories India – 1

Flash back to August 2004 when doctors at the Institute of Immunohaematology, a centre of the Indian Council of Medical Research, used a stem cell therapy developed by the same company, Tristem, to treat four patients with aplastic anaemia at Mumbai's KEM hospital. TriStem's chief scientist, Dr Ilham Saleh Abuljadayel, took white blood cells from each patient and returned "transformed" cells for infusion into the patients. The hospital's ethics committee suspended the study after it discovered that Dr Abuljadayel had posted the patients' photographs on TriStem's website. One patient died in December 2004 from a respiratory infection that, hospital doctors said, was a complication of aplastic anaemia and not the result of the treatment.

It is not clear whether KEM's ethics committee approved the procedures. The Institute of Immunohaematology's director, Dipika Mohanty, said that before the clinical study the institute had conducted animal tests to establish the safety of the transformed cells.

Ganapati Mudur. Indian researchers accused of violating ethical guidelines. BMJ, January 8, 2005.

Stem cell stories India – 2

A private clinic in Delhi announced that it had helped 100 patients suffering from Alzheimer's disease, paralysis and Parkinson's disease using embryonic stem cell therapy. Geeta Shroff of Nu tech Mediworld announced this in the presence of Union Health Secretary P K Hota, Prime Minister Manmohan Singh's wife Gursharan Kaur, and former Chattisgarh Chief Minister Ajit Jogi. Jogi received the procedure for paralysis.

The health secretary said, "My presence does not mean I support it. . . Human life should not be toyed with. We are worried...we will set up a system...No proven medical therapy using embryonic stem cells is available."

Dr Shroff of Nutech Mediworld said all existing government guidelines were being followed in the use of stem cell therapy. "We have been in touch with ICMR and submitted our protocol to ICMR. Details of all cases are sent to them before the therapy is started," she said. Currently, stem cell research falls under the purview of ICMR guidelines on biomedical research and the department of biotechnology's guidelines on stem cell research. Asked about animal studies, she said these were not needed in this area.

Clinic's embryonic stem cell therapy worries govt. Rediff.com, November 16, 2005.

Lining up for business?

Twelve hospitals in India are queuing up for accreditation by the Joint Commission International, a certificate of standard to bring in more foreign medical tourists. It is believed that the National Health Service of the United Kingdom decided not to direct its patients to Indian hospitals because of the lack of accreditation and standardisation. However, hospital managements do not agree that JCI certification is all about medical tourism. "It can only be labelled as a welcome byproduct," said Anne Marie Moncure, managing director of the Apollo Hospital in Delhi.

Malathy Iyer. Indian hospitals queue up for US stamp of approval. The Times of India, Mumbai, September 30, 2005.

Attacks on hospitals – 1

A day after 15-year-old Chhaya died under mysterious circumstances in the municipal Charak Palika hospital in Delhi, her aggrieved relatives attacked the hospital blaming the doctors on duty for her death. Her parents say she was admitted to the hospital for dizziness. The hospital's superintendent says she was injected with diazepam to control a seizure. She died a few minutes later. The municipal chief has ordered an inquiry into the incident.

Times News Network. 15-year-old dies, kin attack hospital. The Times of India, Mumbai, October 24, 2005.

Attacks on hospitals – 2

Doctors of the KJ Somaiya hospital at Chunabatti, Mumbai, went on strike after two of their colleagues were beaten up, allegedly by relatives of a patient. Thirty-year-old Ajit Dudhwadkar died a few hours after admission to the hospital. According to the hospital dean, Mr Dudhwadkar was diagnosed with vivax malaria and died of multi-organ failure. The doctors called off their strike after a meeting with the hospital authorities.

HT correspondent. Dead patient's kin assault docs. Hindustan Times, October 20, 2005.

Attacks on hospitals – 3

Two doctors of the municipal run VN Desai hospital in Santacruz, Mumbai, were assaulted by Buddhan Thakur, whose wife died in the hospital. She had delivered a child 10 days earlier. She developed breathlessness and could not be resuscitated. Doctors suspect that she died because of a clot in her lungs but the exact cause will be known after a post mortem.

Mr Thakur was arrested for attacking on-duty government officials. Twenty-three doctors struck work for two hours. Neighbours of the Thakurs protested outside the hospital. This was the fifth such incident in Mumbai hospitals in 2005. Civic authorities have promised protection to hospital staff.

Times News Network. Man attacks medicos after wife's death. The Times of India, October 22, 2005.

Attacks on hospitals – 4

Starting January 2006, a committee of medical professionals, politicians and media persons will work to avoid attacks on nursing homes and doctors. The Andhra Pradesh Private Hospitals and Nursing Homes Association's president, C Subramaniam, announced this recently.

Staff reporter. 'Healthcare beyond reach of poor'. The Hindu, November 28, 2005.

Insurance against sterilisation 'mishaps'

The union government plans to introduce a family planning insurance scheme for both doctors and patients. The insurance scheme provides for payment of varying amounts of money in the event of death in a hospital due to sterilisation, or in the event of death within 30 days of discharge after sterilisation, in failure of sterilisation and in medical complications arising within 60 days of the operation. The scheme will also provide indemnity insurance to doctors providing sterilisation procedures. The scheme was proposed because doctors fear litigation; there are more than 100 litigation cases in Uttar Pradesh alone.

Sridhar Kumaraswami. Sterilisation: centre plans insurance. Asian Age, Mumbai, November 28, 2005.

Medical disposables reused

"Medical devices that are meant for single use are routinely reused and that too without proper sterilisation," says Bejon Misra of the Delhi-based Voluntary Organisation in Interest of Consumer Education. Voice conducted a sample survey of 16 hospitals in Mumbai and Delhi from August to October 2005 and found gastroenterologists in all the hospitals reusing the single-use biopsy forceps. But doctors said they would not like to reuse the forceps on their own relatives. According to surgeon Sanjay Nagral, "Many accessories that are disposable in nature are reused across specialities... Sterilisation has to be perfect, otherwise you can theoretically pass on infection to patients." Apart from the safety angle, Voice felt there was rampant profiteering. "What are the chances that the patient is told about the reuse and benefits economically?" asked Vijay Jathanna of the Federation of Indian Consumer Coordinators.

Times News Network. 'Use and throw' devices reused in hospitals. The Times of India, November 26, 2005.

Surgical items past expiry date

In Mumbai, even before the row over JJ hospital using unapproved cardiac stents died down, the Food and Drug Administration found that the Breach Candy hospital had a large stock of expired surgical items. An FDA raid found the hospital store stocked expired items in large quantities and even relabelled expired items with new expiry dates. The hospital chief manager stated that all items listed by the FDA had been segregated for destruction after they receive permission.

Prafulla Marpakwar. FDA raids Breach Candy Hospital. *The Times of India*, December 7, 2005.

The pig heart miracle man is back

Nine years ago, he performed the world's first pig-to-human heart transplant and landed in jail. Today, Dr Dhaniram Barua claims that he has a wonder drug which renders bypass surgery redundant and cures most heart ailments without surgery. Dr Baruah claims that the compounds he has developed cure heart disease, diabetes and kidney ailments too. He says he is now working on a vaccine to make young people immune to cardiac ailments. He says his capsules have already cured over 300 patients, including some prominent journalists, lawyers, businessmen and even a doctor.

DH news service. Maverick medic's miracle cure. *Deccan Herald*, Bangalore, October 5, 2005.

Medical education : communal politicking

A bathroom brawl over hot water in the hostel bathroom of the Grant Medical College, Mumbai, turned into a "Maharashtrian versus Biharis" conflict. Moreover, feuding cousins, politicians Raj and Udhav Thackeray, vied with each other against the "Bihari camp". They threatened an agitation if the "nine non-Maharashtrian boys" were not expelled, and competed to stand bail for the Maharashtrian students. The non-Maharashtrian boys were worried about how they would prepare for their exams which were to start on December 13 and worried that they could be targeted by Sainiks while going to the exam hall at KEM hospital.

Somit Sen and Vijay Singh. Bihar students flee JJ campus. Sena gives dean 48 hours to expel nine 'non-Maharashtrians'. *The Times of India*, December 7, 2005.

They practised without a license

On July 7, 2003, Shashikala Vichare was admitted for an emergency caesarean operation at Dr Jog's hospital, Thane. Three days after discharge, she returned to the hospital with chest pains and was told she would have to be hospitalised for two days for the removal of phlegm that accumulated in her chest, this time at the Lok hospital. It would cost Rs 15,000. However, after spending Rs 135,000 in 12 days, she died. The consultant in charge, a Dr Bhawe, said there was no need for a post-mortem and also refused to hand over her case papers. Instead, after two months, her husband, Shashikant received another bill, this time of Rs 335,000.

On November 3, 2003, Shashikant filed complaints at the police station, the consumer court and the Maharashtra Medical Council. Based on the medical council's report, almost exactly two years later, the police filed charges against the six doctors concerned with Shashikala's treatment. It turned out that Dr PB

Jog who administered the anaesthesia was an MBBS and not qualified to administer anaesthesia; Dr Sujata Rathod who had an MBBS degree claimed to have many more degrees and called herself a gynaecologist, obstetrician and infertility consultant; Dr Ganesh Prabhakar Mahajan, the resident medical officer, was a homoeopath. Dr Sachin Barne was a full-time employee of a municipal hospital and therefore was not permitted private practice. Two other doctors, Dr Anand Bhawe and Dr Jaydeep Mehta, were aware that the other doctors were not qualified.

Swati Ali. Wrong treatment leads to patient's death, six doctors arrested. *Indian Express*, November 17, 2005.

Cross-border kidney trade

This is Indo-Pakistani cooperation of another kind. The absence of a law banning a trade in organs has given rise to a flourishing business in transplants of organs bought from poor people. Pakistan is known as Asia's largest kidney bazaar, where the trade takes place openly. The post-quake scenario has added a new dimension to the already shocking trade in human organs in Pakistan. Transplants make hospitals richer by up to \$10,000. Most patients are from the Middle East, the US and the UK but the recent warming in Indo-Pak relations has got Indians coming here as well.

Amir Mir. The Hippocratic curse. *OutlookIndia.com*, November 28, 2005.

Unethical research rewarded?

A scientific paper based on a trial with questionable ethics has won the 'best clinical award' in the 10th International Congress on Oral Cancer in Greece recently. The paper was titled 'Five year survival results of a single group study of intralesional tetra-O-methyl nordihydroguaiaretic acid in oral squamous cell carcinoma (M4N study)'.

This was the controversial trial at the Regional Cancer Centre, Thiruvananthapuram, funded by Johns Hopkins University in the US, and conducted without prior permission from the Drugs Controller of India. The participants were unaware that they were being given an experimental drug, not the standard treatment. The paper does not make reference to the fact that the original study had 27 patients, and some were given an experimental chemical, G4N. The list of authors includes Dr Manoj Pandey and Dr Krishnan Nair of RCC and Prof R C Huang of Johns Hopkins. The picture is unclear. Was this paper based on a trial that was halted for ethical irregularities? If not, how is it that the JHU researcher's name appears on this paper? If so, have the data been presented accurately? According to the RCC when the controversy first broke, the patients were terminally ill. And should unethical research get published – and even rewarded? According to Dr Krishnan Nair, then director of the RCC, "I want to clarify that the paper is not based on any follow-up study. The study was stopped abruptly after the Government of India ordered its suspension (for six months) in 2001. The paper is based on the results obtained till then." The report's author asks: "One question had no immediate answer: Who would benefit from creative, positive data on survival of patients from a condemned clinical trial in India?"

R Krishnakumar. An award and some claims *Frontline*, November 5-18, 2005