

FROM THE PRESS

Stem cells from India

India is tightening regulations on research on human embryonic stem cells to prepare for research within the country as well as possible international projects that might involve embryonic material from India. This follows concern that India could emerge as a major source of embryonic stem cells as there is almost no public or religious debate on abortion, which is legal across India.

A national bioethics panel, set up by India's department of biotechnology, has drafted new guidelines for human genomics research that also cover rules for the collection and use of embryonic stem cells. The panel said that scientists may harvest human embryos for research before day 14 of gestation with the informed consent of the donor. All projects would have to be approved by the national bioethics panel, and researchers would have to share any commercial benefits that emerge from embryonic stem cell lines with the donor.

Senior officials say that the new rules draw on existing ethical guidelines from the Indian Council of Medical Research but that they will be enforceable.

"They have been approved by the law ministry and are intended to be legally binding," said Dr Virender Vinayak, adviser for medical research in the department of biotechnology. Two Indian research centres are among 10 worldwide named by the US National Institutes of Health as holding human stem cell lines that are eligible for US federal research funds. Government officials have said they may need to regulate in vitro fertilisation clinics that are potential sources of embryonic stem cells.

Ganapati Mudur. India to tighten rules on human embryonic stem cells research BMJ September 8, 2001.

AIIMS doing a bad job

India's leading public hospital and medical education centre has failed to provide high quality medical services to its patients, a government audit report has said.

A shortage of doctors and infrastructure deficiencies at the All India Institute of Medical Sciences, New Delhi, is depriving patients of quality time in diagnosis and medical care, the report by India's auditor general said.

An outpatient at the institute on average gets four to nine minutes of attention from a doctor, while the waiting time for surgery ranges from two to 34 months, it said. And at least three patients terminally ill with cancer are turned away each day for lack of healthcare facilities.

The report also said the institute failed to nurture trained medical professionals and stop the 'brain drain'. The government subsidises medical education at the institute, but 49 per cent of a sample of 390 doctors who had trained there had emigrated.

"The patient load we get is the price we're paying for our efficiency," said Dr Pradeep Kumar Dave, director of the institute. The outpatient department, originally designed to cater for 500 patients a day, now receives nearly 6,000 each day.

The institute is India's most attractive site for medical education, with more than 35,000 candidates taking a screening examination for the institute's undergraduate medical degree programme that accepts 50 students each year.

Dr Dave said that the institute could not be expected to exercise control over students who prefer to emigrate. Health policy analysts say that the situation at the institute merely exemplifies the deterioration of health care services in the government sector. "An institution intended for tertiary care has been reduced to a general hospital," said Alok Mukhopadhyay, executive director of India's Voluntary Health Association.

Ganapati Mudur. Auditors slate top Indian medical centre. BMJ September 8, 2001.

'But it was legal then...'

The law is clear: you cannot conduct or 'cause to conduct' a test to find out the sex of your foetus. If you do so, you can be imprisoned for up to three years. But the Prenatal Diagnostic Techniques (PNDT) Regulation Act came into effect only five years ago, and that's why a couple in Surat and their doctors are very lucky.

For not only did they determine the sex of the foetus, they aborted it when told it was female. After the abortion, when the parents discovered that the foetus was male, they dragged the doctors to the consumer court and were recently awarded damages with interest. In October 1992, Rita Jadhav, resident of Dhova village in Bhavnagar and a mother of three daughters, wanted a male child and so she consulted gynaecologist Sushma Iyer when she became pregnant for the fourth time. Iyer sent the uterine fluid sample to Surat-based pathologist Nirmal Vaniwala who identified the foetus as a female.

The couple came back to Iyer saying they wanted a second test to confirm the findings but Iyer suggested an abortion going by Vaniwala's report.

The couple could not afford Iyer's abortion fees so they went to the local SDVS Ashaktashram hospital and had an abortion done. The doctor who conducted the abortion told them the foetus was a male.

The distressed couple approached Jagrut Nagrik, a consumer-protection organisation in Vadodara, and filed a case against the Surat-based gynaecologist and pathologist with the State Consumer Disputes Redressal Commission. They accused the doctors of negligence and violation of medical ethics. PV Moorjani, Jagrut Nagrik secretary who filed the case, claimed a compensation of just over Rs 10 lakh.

The commission, in its order in July, observed that there was collusion between the gynaecologist and the pathologist which prevented a second test. The commission also observed that both the doctors were registered with the Medical Council and had performed a sex determination test though it was against medical ethics, and this amounted to medical negligence.

The two doctors were directed to pay Rs 25,000 with 10 per cent interest within four weeks of the order to the parents.

"We have only seen the case from the scientific point of view and the doctor should have conducted the test carefully," said Justice Mahendrabhai Parikh, chief of the commission who delivered the verdict. Justice Parikh declined to comment on the case saying that the judgement speaks for itself and only the High Court can take up the matter. He added that in this particular case the "sex determination test may have been done before it was banned." Under existing law the story would have been quite different. "This is a criminal case and both the parents and the doctors can be imprisoned and fined for breaking the law," says A R Nanda, union secretary of family welfare.

For not only are sex determination tests 'against medical ethics', as the commission has noted in its judgement, the PNDT Act clearly makes it illegal. It notes that prenatal procedures should be only done to determine 'chromosomal abnormalities, genetic metabolic disease, haemoglobinopathies, sex-linked genetic diseases and congenital abnormalities', and that "no person conducting prenatal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives the sex of the foetus by words, signs or in any other manner."

Under the offences and penalties section, the Act says that the guilty shall be punished with imprisonment for a term which may extend to three years with fine which may extend to Rs 10,000. Under the Act, not only are the doctors guilty for telling the parents the sex of the foetus, but the parents are as guilty of seeking the sex determination test for the obvious purpose of aborting the girl child.

"There is clear evidence against both the doctors and the parents in the case and the appropriate authorities, who are empowered to implement the PNDT Act, should take action against both parties for breaking the law," says Nanda.

Ayesha Khan and Sanchita Sharma. When foeticide gets you money from the court. Indian Express, August 5, 2001.

Kidney trade

In response to a petition filed in the Bombay High Court by surgeon Dr Mahesh Jukar, challenging the nine charges framed against him by a lower court, for illegal kidney transplantation, the state argued that there was substantial evidence to prove that Dr Jukar was actively involved in illegal surgeries and pointed out evidence that warrants conviction.

The case refers to a flourishing kidney transplantation racket at an Ayurvedic dispensary by the name of Kaushalya Nursing Home in Linking Road, Khar, which was owned by Dr Santosh Raut, main accused in the case. The dispensary was started in 1989 and Dr Raut, through agents, would bring people from Gulf countries for kidney transplantation. Agents would, under false excuses, also bring donors - who would in most cases be illiterate and poor people. While the donors would get Rs 40,000, Dr Raut would get money in dollars. The amount received by the agents would be between Rs 30,000 and Rs 35,000 while Dr Raut would get anything between Rs 2.5 lakh and Rs 3.75 lakh. The patients would come from countries like Turkey, Greece, Saudi Arabia, Yugoslavia, etc.

Prior to 1994, Dr Raut had a surgeon by the name of Dr Yogesh Kothari to help him in the transplantation as Dr Raut himself was not a qualified surgeon. The dispensary also had no license for surgery. From 1994 onwards, Dr Raut employed two surgeons - Dr Mahesh Jukar and R Abhay Dalvi - to do the transplantation. Dr Dalvi was attached to KEM hospital. Besides these two surgeons, Dr Vishwas Sane and Dr Dilip Rana were employed as anaesthetists. The modus operandi would be simple - while Dr Jukar attended to the donor to remove the kidney, Dr Dalvi and Dr Raut would be with the recipient. Approximately 225 cases were done in this manner by Dr Raut.

After the dispensary was raided by the crime branch and various charges were filed, Dr Jukar approached the court for a discharge. He stated that he was a young man in the beginning of his career and he used to go for surgery to learn from other doctors. He also argued that it was not his dispensary and he used to go only when he was called and, hence, the prosecution should not be believed and he should also be discharged. Among the evidence the prosecution pointed to was that the register showed that more than 100 cases were done by Dr Jukar, all referred by Dr Raut.

Correspondent. State defies surgeon plea, says evidence proves the crime: illegal transplant racket. Asian Age, August 13, 2001.

Call to probe trials

The Consumer Education and Research Society (CERS), Ahmedabad, has petitioned the National Human Rights Commission (NHRC) for a probe into testing of experimental drugs on unsuspecting patients in violation of ethical and medical norms.

The CERS petition follows reports of more than 20 clinical evaluations of new drugs being conducted in India, on human subjects and patients. Many of these studies were unauthorised and not properly monitored by competent regulatory medical or ethics bodies, it added. In fact, the patients or the persons on whom the drugs were being tested were not made aware of the risks involved.

"It is highly unethical to carry out clinical trials on humans without explaining to them the risks involved in a language they understand and their consent taken in writing before witnesses," CERS said. In this connection, it referred to the tests conducted on the 'hapless patients' at the Regional Cancer Centre (RCC) at Thiruvananthapuram in Kerala and the Metro Hospital in New Delhi.

CERS also referred to New Delhi's metro hospital where Dr Purshottam Lal injected vascular endothelial growth factor into 11 heart patients without informing them of the risks involved.

In a press release, CERS pointed out that the Indian Council of Medical Research (ICMR) has adopted elaborate ethical guidelines for biomedical research including clinical trials on humans and said these tests have to be undertaken with the prior permission of the DGCI. Further, the clinical tests are to be monitored at the site of the test by an appropriately constituted institutional ethics committee (IEC).

"CERS is concerned about the alleged human rights violation of the patients who have received these experimental drugs without their written consent, without their knowledge and without following the established guidelines for these tests and of course, prior permission of the DGCI. It is possible that the IEC did not perform its expected duty by strictly monitoring these clinical studies on patients," the petition said.

Though the Kerala state government has constituted an enquiry under Dr Purvesh Parikh to look into the RCC experiments, the NHRC will have to investigate the issue in its entirety, CERS said.

It called upon the NHRC to see that the DGCI submits a list of all the clinical trials being conducted on humans and the names of the clinical centres where these are conducted in the country.

Times News Network. NHRC urged to investigate testing of drugs on patients. The Times of India, August 28, 2001.

Without comment

Union health minister Dr C P Thakur has made a very strange request to the finance ministry: exempt all doctors in Bihar from paying income tax as they were paying 'protection money' to criminals in the state. Dr Thakur also appealed to Union home minister L K Advani to intervene and protect the doctors and common man in Bihar.

UNI. 'Bihar doctors must get tax exemption'. Asian Age, September 28, 2001.

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