

'Cross prescription''

The Maharashtra Food and Drug Administration (FDA), attempting to enforce the ruling by the Supreme Court, issued an order in the end of December 1996 prohibiting the pharmaceutical trade from honouring prescriptions from doctors registered under one discipline including drugs from any other discipline. The FDA has also warned members of the pharmaceutical trade that any violation of the order would invite prosecution under the Drugs and Cosmetics Act 1940 and/or the Indian Penal Code.

The FDA in Gujarat was the first to issue such orders. The health department, Government of Gujarat has banned the practice of different forms of medicine by any doctor.

The Maharashtra health secretariat is under pressure to implement a similar ban but fears an immediate collapse of its primary health centres where 25% of the doctors have trained in ayurveda. As doctors with MBBS are reluctant to go to rural and tribal areas, the state government has downgraded some class II posts in tribal areas and appointed class III ayurvedic doctors. These doctors are given short-term crash courses in pharmacology before they are allowed to man their centres.

The first Indian porcine xenotransplant

The Press Guwahati (PTI) transmitted this report on 2 December 1996: In a *volte face*, controversial heart surgeon Dhani Ram Baruah, who claimed to have transplanted a pig's heart to a human being on December 15 here, today denied the transplantation saying he only repaired two holes in the patient's heart.

Official sources, quoting the doctor, said today as the holes were repaired Dr Baruah did not have to use the animal's heart as planned earlier.

Meanwhile, the inquiry committee appointed by the Assam government to look into the controversy, today visited the Dr Baruah Heart Institute and Research Centre at Sonapur near here.

Though the doctor initially fended off the investigators, he relented when told the team was accompanied by a magistrate.

On December 18, the hospital staff did not allow the inquiry committee into the hospital. Dr Baruah also refused to meet it.

Incidentally, apart from personally telling journalists that he did transplant the pig's heart, Dr Baruah had claimed the same in a

television interview.

He has invited the local medical fraternity to challenge him at the world conference of heart surgeons in Barcelona, Spain, in July, according to a local English daily, The North-East Times, today. He told the paper over telephone yesterday he planned to present his patient, Mr Purna Saikia (32), along with his papers in Barcelona if he was fit by then.

Reacting to the doubts over the authenticity of his claim, the doctor said he could keep an isolated heart of an animal beating for hours in his laboratory.

Meanwhile, the patient's relatives complained to journalists they were not being allowed to either see him nor enter the hospital premises.

The first Indian porcine xenotransplant (continued)

Amidst a raging controversy in medical and lay circles, the Assam government has ordered an official inquiry into whether a pig's heart was actually transplanted into a human being at a hospital near Guwahati last Sunday.

The so-called 'unique surgical feat' was claimed to have been carried out successfully by Dr Dhaniram Baruah assisted by a team of 16 doctors including two veterinary surgeons at his heart institute and research centre located at Sonapur, about 25 km from Guwahati. The patient was one Puna Saikia (32) from Golaghat.

What made the event highly suspect in the eyes of most of the medical fraternity as well as the local media was that Dr Dhaniram Baruah had rung up newspapers and news agencies well before the operation asking for reporters and photographers to be present to record the 'historic feat.'

While most of the media expressed **scepticism** given the elementary state of cardiac facilities available in the north-eastern region, two local newspapers made a media circus out of the so-called transplant operation.

These two newspapers not only published 'curtain raisers' boosting Dr. Baruah a day before the operation but also published photographs of the patient and the pig on the operating table while the surgical procedure was being carried out. Pictures of the patient recovering after surgery were also published.

The published accounts, however, did not make it clear whether a pig's heart was actually transplanted into the patient. It would appear that what was actually performed was an operation to repair a hole in the heart ventricle. Dr Baruah himself and other doctors associated with the so-called 'transplant' would give only evasive replies to media queries after the first reports were published by the two newspapers.

What made matters worse was that a national news agency picked up the reports in the local newspapers and circulated them both nationally and internationally.

Rival newspapers quoting other cardiac specialists here termed the 'pig-to-man' heart transplant operation a hoax and fraud. Dr Baruah had earlier received much all-India publicity by claiming to have invented a new type of heart valve and an artificial heart.

He was also in the news last August for confining three engineers of a medical equipment company at gunpoint in his heart institute demanding compensation of Rs.8.5 lakh for allegedly supplying defective equipment. Following a complaint by the company, police obtained an arrest warrant for Dr. Baruah who obtained anticipatory bail. He was charge-sheeted in the case at the end of November.

Reputed cardiologists here have termed Dr Baruah's claim of having transplanted a pig's heart into a man as a hoax and a publicity stunt.

'In the entire north-eastern region there are no facilities even to carry out an angiogram. Patients have to travel to Delhi or Madras for a heart by-pass operation. How can this man claim to have transplanted a pig's heart into a man? What facilities does he have in his institute?' asked an eminent cardiologist.

'Such claims give a bad name. to the medical profession as a whole and Indian scientists in particular,' said Dr. A. K. Baruah, Principal of the Guwahati Medical College and himself an eminent cardiologist. 'This is nothing but a publicity stunt.' Several other cardiac specialists expressed similar views, some even questioning Dr. Dhaniram Baruah's professional credentials.

Interestingly, the news of the pig-to-man transplant came out even as it was reported that the British government had put off the first scheduled transplants of pig organs into human beings for fear of animal

viruses being carried over into humans.

Alarmed by the uproar over the whole affair, the Assam Government ordered an enquiry into whether a pig's heart was actually transplanted into a human being.

The enquiry committee, comprising Dr. Ramesh Verma, joint director of health K. N. Das and Professor of Cardiology B. K. Das of the Guwahati Medical College, visited the Dhaniram Baruah Heart Institute and Research Centre on Wednesday to begin their investigation.

They were denied entry at the gate. Dr Baruah and other doctors at the institute also refused to meet the enquiry team saying they were too busy attending to the patient.

Dr Baruah has also threatened to slap a Rs.50 crore suit against the national news agency concerned for allegedly 'misreporting' the surgical procedure carried out. The agency, however, says it had reported on the basis of a press release issued by Dr. Baruah.

The first Indian porcine xenotransplant (continued)⁴

It is as if it had never happened. Called a fraud by the State Government, Dhani Ram Baruah withdrew his fantastic claim that he had 'successfully transplanted the heart of a pig in a man'. Today, barely a fortnight after the outcry died down, the doctor is back to his experiments.

His guinea pig is 32-year-old Purna Saikia; whom he advertised as the recipient of a pig's heart. Today, Saikia lies unconscious in 'Heart City', Baruah's heart care centre at Sonapur, 20 km from Guwahati. Baruah has got the family to sign another 'bond' which permits him to perform a second transplant of a pig's heart.

According to his relatives, Purna was quite hale and hearty before the mysterious 12-hour operation that Baruah conducted on 15 December. 'On 15 December, we were treated to a meal of pork and rice,' recalls Someshwar. 'The hospital cook told us the meat was from the pig killed for the heart.'

Today, Saikia's family is worried. 'On 21 December we were informed that his condition had become serious and that he had lost consciousness. We have not been permitted to see him again,' says Someshwar, Purna's eldest brother.

The Saikias are middle-class farmers from Golaghat in Upper Assam. Purna is the third of five brothers. Afflicted with a congenital heart problem, he seems to have been the victim of typical apathy with which doctors regard poor patients.

It was a newspaper advertisement which drew the Saikias to 'Heart City'. 'After a

preliminary check-up, Baruah admitted him and a few days later we signed the first bond for the operation', says Prafulla Gogoi, a relative. Curiously, Baruah did not think it necessary to explain to the Saikias what a 'pig heart transplant' meant.

The Saikias say they paid Baruah Rs. 1,00,000 for the operation.

Despite several attempts Baruah could not be contacted. His hospital is heavily guarded and no outsider is allowed access.

Health Minister Kamla Kalita, in his statement to the State Assembly said on 23 December that the Government 'was examining all legal possibilities so that adequate action can be taken against him for trying to sensationalise the issue.'

The first Indian porcine xenotransplant (continued)⁵

Three doctors who had claimed to have transplanted pigs organs in a patient were arrested late on Thursday (9 January) night. The doctors, Dhani Ram Baruah, Jonathan Ho and C. J. James were produced before the court of the chief judicial magistrate of Kamrup on Friday where their bail pleas were rejected.

The magistrate said in his order that such transplantations were 'not allowed under the provisions of the Transplantation of Human Organs Act. The case was registered under Section 304, IPC and Section 18 of the Act.

Counsel for Dr. Baruah said that his (Dr. Baruah's) action was not covered by the organ transplantation act as it covered human organs while in this case, pig's organs were involved. The transplantation was done in good faith and the consent of the relatives of the patient was obtained.

Doctors carrying out the postmortem (examination) on Purna Saikia's body refused to give details on the grounds that the case was *sub judice*.

The first Indian porcine xenotransplant (continued)⁶

Talking to the reporter from **India Today** after transplanting a pig's heart into Purna Saikia, Dr. Dhani Ram Baruah said, 'Medical science has taken a giant leap forward. Baruah claimed he used a secret solution of chemicals that blinds the immune system. Saikia's heart was treated with the magic solution for 30 minutes, washed and then implanted in the E-hour operation, Baruah explained. Baruah disowned a subsequent statement which said that he had transplanted a pig's heart, stating that the confession was signed only because they threatened to close down his hospital if he did not do so.

India Today learned that Drs. Baruah and

Ho have achieved infamy in the past. They implanted heart valves made of animal tissue - developed by Dr. Baruah - in 12 patients in Hong Kong in 1992. A year later six patients died. The **Asian Medical News** reported that 'grave concerns were expressed over the procedure and ethics of the implantation'.

When Dr. Baruah was asked about the ethics of his transplantation of the pig's heart, he said angrily: 'To hell with controversies. I will go ahead with what I am supposed to do.'

The first Indian porcine xenotransplant (continued)⁷

The death of 32-year-old Purna Saikia following a controversial pig-to-man heart, kidney and lungs transplant surgery done by Dr. Dhani Ram Baruah along with his associates Dr. Jonathan Ho of the Hong Kong-based Prince of Wales Medical Institute and Dr. C. S. James, raises the basic issues of public morality, professional ethics and the challenges facing law enforcement agencies in a fast changing technological environment. Dr. Baruah and his colleagues have since been arrested by the local police for alleged violation of the Transplantation of Human Organs Act, 1994. Findings of the post-mortem done on the body of Saikia by a medical team are not available yet.

The veracity of Dr. Baruah's claim that the patient died a week after the operation can be proved only by the post-mortem results. Dr. Baruah has also claimed that he had the consent of the patient for the pig heart transplant but this does not absolve him of the responsibility for the serious consequences of the surgery which was plainly illegal as the law does not permit transplantation of an animal organ in a human being. On his part, Dr. Baruah has asserted that the operation was not only successful but also unique and that the patient had responded to the treatment well. He has attributed Saikia's death to secondary causes arising from infection. The public uproar over Saikia's death has predictably caused much embarrassment to the Government and the State Health Minister has even suspected 'fraud' on the part of the doctor in performing the operation.

The episode has naturally attracted worldwide attention for obvious reasons. As the eminent cardiac surgeon, who is heading the Madras Medical Mission, Dr. K. M. Cherian, says, lack of transparency on the part of medical professionals in conducting new experiments could pose a serious threat to public health. A North American organisation planned to undertake transplantation with transgenic pigs, but according to the latest information, it has postponed the experiment. The acceptance

of the animal organ by the human body is yet to be fully established.

In view of the revolutionary strides made in cadaver transplantation and cardiac surgery, controversial experiments should be overseen by a technical committee of specialists to ensure that the law is not violated. Professional and government-run institutions should also be vigilant in protecting the public interest by taking penal action against unscrupulous and misguided professionals. Political intervention to protect the guilty can only harm the medical profession. The Cuwahati episode should be an eye-opener as the legal and ethical issues it raises need to be addressed by the specialists and the authorities. The future of the transplant surgery hinges on the response of the professional and government agencies in guiding its development on the right course.

The first Indian porcine xenotransplant (continued) *

After being released on bail, Dr. Dhani Ram Baruah claimed he would prove his achievement before the international medical community. Dr. Baruah said Purna Saikia had died seven days after the transplant operation due to bacterial infection he had acquired earlier.

He announced his plans to travel to Barcelona and Sydney to present his achievements before cardiac surgeons. He claimed that his success lay in preventing hyperacute rejection of the pig organs using his antigen-suppressing agent. He felt that his experiments with **xeno**-transplantation should not stop just because there were chances of infectious disease being transferred to the patient. 'If any unknown virus is transferred to human beings from pigs, the virologist can take care of it,' he stated.

Dr. Baruah alleged that there was an international conspiracy to undermine his achievement. He said he would seek the permission of the Indian Medical Council to perform more such operations.

Death following endoscopy *

Three-and-a-half-year-old Altamash Shaikh swallowed a **50-paise** coin whilst playing with his friends. His parents panicked although Altamash did not complain of any uneasiness. They rushed him to a general practitioner who advised an x-ray. 'Following his advice, he took him to the **Linkway** Nursing Home and Polyclinic situated at Link Road, Behrambaug (Jogeshwari, Mumbai) and approached Dr. **Amar** Singh in the x-ray department. The report confirmed that there was a coin in the stomach. We were very concerned,' said. Altamash's father, Akbar-

Shehnaz, Altamash's mother, says she asked Dr. Singh whether giving their son bananas or an enema would help bring the coin out. He turned down their suggestion and insisted they go in for endoscopy. The parents hadn't yet decided what to do and were still waiting for their relatives to advise them when Dr. Shankar **Sawant** went ahead with the procedure. Dr. Renuka Anvekar anaesthetised their son after coercing them to consent, say the Shaikhs.

The operation started at 10 p.m. At about 1 a.m. Dr. **Sawant** came out of surgery and informed us that Altamash had died on the operating table. 'His mother almost collapsed and I became numb on hearing that', said Akbar.

Dr. **Sawant**, when contacted by Bombay *Times* said that he had performed the operation in good faith and didn't know what had gone wrong. 'The *post-mortem* report has yet to come and so I can't comment on anything', he stated.

Akbar Shaikh approached the Oshiwara Police Station to register a case of negligence. But according to Oshiwara police officials, no case can be registered until the *post-mortem* report is out and the cause of death is known.

Eye Institute experiments on blind boys with grisly cocktail **

Medical authorities have warned a private eye hospital in Hyderabad where doctors were using students of a local blind school as guinea pigs in transplant surgery, ostensibly to restore their sight.

The Indian Council of Medical Research (ICMR) directed the L V Prasad Eye Institute to stop further experiments on the blind which it says are in violation of ethical guidelines for experimenting on humans.

The institute has so far used eight blind boys in an experiment to find out if injecting brains cells of aborted fetuses into the retina restored their sight that was lost due to a progressive disease called retinitis pigmentosa. The doctors claimed to have obtained **clearance** from a local ethical committee.

While there is no documented evidence of any of the boys regaining their sight, the doctors wanted to try this technique on 20 more patients when ICMR put a stop to the project.

The Institute carried out its project in collaboration with some institutions in the United States where such experiments involving foetal cells are not permitted. India, incidentally, has no law governing the use of foetal cells for research;

According Dr **Tara** Prasad Das who performed the transplant, 14-week-old

foetuses needed for the experiment were made available by the Government Maternity Hospital in Hyderabad.

The experiment involved extracting the neural cells of the foetus and introducing these behind the retina of blind persons through tiny holes made in their eye balls. The idea was that growing neural cells would replace the defective retinal cells of the patient, resulting in restoration of vision.

It is not known if animal studies were ever done and whether animal data had compelling evidence to warrant human trial, an ICMR official said. It is also not known how the institute obtained the mandatory consent of the patients who cannot see what they sign.

The L V Prasad Eye Institute had earlier been in trouble over export of blood samples of its patients to an American agency under the garb of foreign collaboration. These exports, which were without official permission, were also stopped by ICMR which is the nodal agency for clearance of any foreign collaboration involving transfer of human material.

India not to allow medical experiments on human beings "

In a statement issued to clarify its stand on an experiment being conducted on the blind by the L V Prasad Eye Institute (LVPEI) in Hyderabad with the US assistance, the Indian Council of Medical Research (ICMR) said such trials were not ethical and similar experiments would not have been allowed in the US.

The Hyderabad institute was recently in the news for conducting tests on several patients affected by retinitis pigmentosa, a hereditary disease, using a new clinical method where foetal tissues were used for transplantation.

The ICMR said however, that it does not have the authority to stop an experiment, unless it funds or sponsors the project. 'The Council came into the picture only when the Institute submitted a new research proposal for financial support under the **Indo- US** collaborative programme,' the statement said.

All international/joint research proposals that ICMR get is first examined by technical experts or subject specialists and finally by a high-powered committee under the Ministry of Health and Family Welfare. The proposal by LVPEI was considered by the high-powered committee, but not approved on the grounds that '...**undertaking** such clinical trials on Indian subjects for an experimental procedure which was not being carried out on the US subjects was not ethical and hence not

acceptable.' This decision was later communicated to the principal investigator of the proposal.

Fallen doctors ¹²

The physician-patient relationship has undergone a massive change. No longer is a patient treated with care and compassion by the physician despite the astronomical increase in the consulting fee. For the doctor, the patient is just another nameless person to be subjected to a series of queries and tests.

It is indeed a pity that most doctors have forgotten their primary responsibility towards the patient. The sacred trust reposed by the sick and helpless patient in the doctor is commercially exploited to the hilt by the entire system of medical practitioners, diagnostic professionals, surgeons, nursing staff and others. Most in the medical profession are just interested in acquiring wealth at the cost of the ignorant patients. In this pursuit the physician is least bothered if the patient is put to needless surgical and diagnostic procedures and 'therapeutic over-prescription'.

These practices have alienated the doctor from the patient who now views this 'unsympathetic group as one to be visited only in desperation'.

Increasing mechanisation and reliance of modern diagnostic aids has not only benumbed the doctor's clinical acumen but has increased the costs.

Medical practice in Madhya Pradesh ¹³

Bravo to the M.P. Govt. for stopping the private practice of medical doctors in cities. But let us see how long the Govt. can and really sustain it or the situation will deteriorate to having the cake and eating it too when the medical doctors in cities will earn with their salary the "non-practising all0 wance" (which should be stopped anyhow) and have (illegal) private practice secretly. Or the medical doctors will just "feed" the authori ties and politicians and get the decision reversed. But I really want to dispel the following delusion in the mind of some that " this...would lead to an exodus of talent from the ranks of government doctors" (as said by the President of the Government Doctors' Association-who else-vested interest and trade unionism are transparent here). My honest reaction as a common Indian is: Good riddance. Go. Resign, and hundreds will apply to replace the so called "talent" (to do practice of what type is an open secret). India does not lack talent.

From: Ratan <ratana@kb.usm.my>

Hoodwinking the Medical Council of India and the University of Bombay in the name of Mahatma Gandhi ¹⁴

Wards with rows of empty beds, a doctor living in a mortuary and perfectly healthy 'patients' checking in for 'treatment'. These are some of the more startling aspects of two of the hospitals owned by the Mahatma Gandhi Memorial Trust in Navi Mumbai.

The MGM Medical College and four associated hospitals were recognised by the Medical Council of India (MCI) in 1994. MCI rules require periodic inspections to ensure that these hospitals have all the appropriate facilities for medical students. Several of these facilities are either missing or lying unused at these institutions. And it is only on the eve of an inspection from the Mumbai Vidyapeeth that the authorities launch their operation to maintain the minimum bed-occupancy level.

One such inspection was scheduled on January 16. When *Express Newsl ine* visited the hospitals on January 15, there was feverish activity. 'Patients' were being brought in to fill rows of empty beds. A Hospital employee was seen luring prospective patients. 'If you know of anyone who's ill, bring them along. A child's bloated stomach, fever, cough, even a scratch on the leg will do,' he said. Twenty workers from a construction site in Nerul were picked up in this manner. A few of these patients seemed genuinely ill, the others looked hale and hearty. The 'patients' were paid Rs. 50 each and provided free breakfast and meals for their service. The deals are made through a Nerul-based agent.

MGM dean, S. D. Nadkarni and director S. N. Kadam denied that such pre-inspection activities were carried out.

The charade does not end at importing patients. On January 15, *Express Newsl ine* photographer Neeraj Priyadarshi took pictures of a building which, a' board proclaimed, was the mortuary. But when the *Newsl ine* team went there again later, the mortuary was nowhere in sight. In its place was the residence of Dr. Anil S. Mane. R. C. Sharma, the officer on duty said a resident doctor was being allowed to live in the premises earmarked for a mortuary. 'We do not have permission to conduct post-mortems here. So bodies are sent to Panvel for the purpose. So we don't really need a mortuary.' The exception, of course, being the day when the university inspectors come calling. (*Express Newsl ine* has published photographs of the mortuary-turned-residence under the caption *Death and life*.)

Sharma admitted that at any given time, at the most, only 150 of the 550 beds are

occupied. On January 18, there were barely 11 patients in the 150-bed Gynaecological and Paediatric Hospital at Kalamboli and 56 in the 550-bed Kamothe Hospital.

And the watchdogs slumber on... ¹⁵

The advances of medical technology have not only helped doctors in the diagnosis of very complicated diseases but have also provided them an avenue to make quick bucks. The situation has disproved the theory that when competition exists, prices come down. Huge sums are being invested in the setting up of diagnostic centres and the only way to earn returns is by ensuring a regular flow of referrals from' doctors through the practice of paying a commission to them.

When certain tests are advised, the doctor directs the patient to specific diagnostic centres and insists that the tests be done there. A computerised tomographic (CT) scan can cost anything from Rs. 2000 upwards and a bulk of this goes back to the doctor as a kick-back fee.

Some members of the medical fraternity have attempted to raise the issue and get the government to take action. Chief nephrologist of Apollo Hospitals, Dr. M. K. Mani informed the Medical Council of India about these unhealthy practices more than a year ago. The Medical Council confirms that fee-splitting is an offence. But till such time as action is taken the virulence of the kick-back virus will continue to worsen.

False medical prescriptions"

Seven insurance medical practitioners of Employees' State Insurance Scheme (ESIS) hospitals... were arrested on Saturday by the city police for allegedly misappropriating government money to the tune of thousands of rupees.

The names of the doctors were given as Krishnaji Atmaram Wechlekar (64), Narayan Venkateshwar Boravanch (66), Kantilal Ramjibhai Desai (58), Shobhanath Ramsunder Tiwari (72), Rameshchandra Kantaprasad Nigam (58), Santbaxi Ramvilas Dubey (62) and Bansidhar Ghanshyam Mehta (68).

Assistant police inspector Nandkishor More said, 'A complaint was lodged by the ESIS...against the medical practitioners... They are accused of producing false medical bills and withdrawing money illegally from ESIS hospitals under the government's medical benefit scheme.'

The surgeon with HIV ¹⁷

A Glasgow surgeon became the first doctor in Britain infected with HIV to receive the all-clear to resume surgical practice. The West Glasgow NHS Trust set up a special working committee to consider patient

safety as well as medical, ethical and legal issues. This landmark decision by the Trust gives hope to infected health workers. No British health worker has ever transmitted HIV to a patient. There is much more likelihood of a worker catching the virus because of the exposure to blood from an infected patient.

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