FROM THE PRESS

An error is not the same as negligence

The Supreme Court has held that a doctor cannot be held liable for medical negligence just because a patient did not respond to treatment or the surgery failed. The Court set aside an order passed by the National Consumer Disputes Redress Commission, which held Dr Martin F D'Souza of the Nanavati Hospital, Mumbai, guilty of negligence on a complaint from Mohommad Ishfaq, who was treated for renal and severe urinary tract infection.

Justices Katju and RM Lodha said a doctor could be held liable "only where his conduct fell below the standards of a reasonably competent practitioner in his field". The judges clarified that they did not hold any sympathy for errant doctors who caused death or agony due to negligence. Such doctors would be strictly penalised. However, this judgement was essential to protect doctors from harassment.

The judgement requires that any complaint against a doctor or hospital must first be referred to a competent doctor or a committee of doctors. The judges stated that this was necessary because consumer forums or criminal courts are not experts in cases of medical science and specialists' advice is essential. Only if the doctor or committee holds it to be a case of negligence would a notice be issued to the doctor or hospital.

J Venkatesan. Doctors can't be held liable for error of judgement. *The Hindu*, February 19, 2009

Not without my consent

The Supreme Court has stated that doctors must seek consent from patients before conducting any procedure additional to the scheduled surgery for which they have received consent. Justices B N Agrawal, P P Naolekar and R V Raveendran stated that only in an emergency, when the life of the patient was in danger without immediate surgery, would the consent of the patient's relative suffice. In all other cases doctors may not conduct additional surgery until after the patient regained consciousness, was informed of the need for additional surgery, and gave consent.

The ruling was in the case of a patient whose ovaries were removed during a diagnostic procedure. Dr Prabha Manchanda who conducted the procedure stated that since the patient was not conscious during the diagnostic procedure, she asked for and received consent for this additional procedure from the patient's relative.

The court noted the widespread public perception that private hospitals and nursing homes tend to inflate bills by carrying out several additional procedures during a scheduled operation by obtaining consent of the patient's relative while the patient is in the operating theatre.

Dhananjay Mahapatra. Patient's consent must for all operations: SC. *The Times of India*, January 17, 2008

Forensic evidence under scrutiny

For over a century forensic evidence has been upheld as a reliable methodology for use in criminal investigation. However a February 2009 report by the US National Academy of Sciences has questioned the accuracy and reliability of both forensic evidence and the way it is collected.

This report states that the field uses outmoded and untested theories by analysts who often have no background in science. Evidence is often handled by poorly trained technicians who overemphasise the accuracy of their methods in their testimonies in court. The report documents numerous cases in which people were wrongly arrested and wrongly convicted. A study of trial transcripts of 137 convictions overturned by DNA evidence found that 60% included false or misleading statements regarding blood, hair, bite mark, shoe print, soil, fibre and fingerprint analyses.

Legal experts anticipate that this report will give lawyers a chance to challenge decisions in cases that relied on such investigations to convict their clients.

Solomon Moore. Science found wanting in nation's crime labs. *The New York Times*, February 4, 2009

GSK offers to make drugs available in "poorest countries"

The chief executive of GlaxoSmithKline (GSK) has outlined a proposal to share some of the company's patents to boost research into neglected diseases and make its drugs available more cheaply in "the poorest" countries.

Andrew Witty offered to open up GSK's research centre for neglected diseases at Tres Cantos in Spain to other researchers, companies and governments. He stated that the company's aim was to foster a global public-private network to supplant research efforts on neglected diseases such as sleeping sickness, visceral leishmaniasis and dengue fever.

GSK's proposal includes the creation of a "patent pool" for drugs and manufacturing processes related to neglected tropical diseases. Researchers and companies, including manufacturers of generic drugs, would be able to license participants' patents from the pool, for free, to develop new treatments for neglected diseases in under-developed countries.

The patent-pool proposal has sparked controversy because it excludes GSK's HIV patents, as the company feels that there is already enough research in this area. The company's claim is hotly contested by Médecins Sans Frontières' Campaign for Access to Essential Medicines. MSF has stated that there

is still a great need for new antiretroviral combinations and formulations for children.

Several big drug companies are also sceptical of GSK's proposal. SanofiAventis says that the proposals are "too vague", while Novartis "does not consider intellectual property as an obstacle to access to medicines". Western drug companies fret that such licences could limit their opportunities in what they see as their biggest future growth markets: the well-off elites in emerging economies such as India, China or Brazil. Preserving these markets may explain why GSK has limited its proposals to the least developed countries.

Declan Butler. Drug patent plan gets mixed reviews. *Nature*, February 23, 2009

Ethics review: is there a monitor out there?

A hospital technician in Malawi has been accused of conducting chemotherapy drug trials without permission. Thadeo Mac'osano coordinated a hospital's Palliative Care Unit at St Luke's hospital in southern Malawi. He was arrested in October 2008 after he provided the hospital with the preliminary results of experiments conducted on people with HIV and the related cancer, Kaposi's sarcoma. Six patients who were part of these trials died though it is not known whether these deaths were due to the experimental drugs.

Mac'osano faces four charges including conducting clinical trials without permission from Malawi's Pharmacy Medicine and Poison Board (PMPB) or the National Health Sciences Research Committee (NHSRC); administering medication without the correct licences; and conducting drug tests on patients without their informed consent. He has pleaded not guilty to all charges.

A number of questions are being asked following Mac'osano's arrest. How did he get access to the drugs? Should the hospital have informed patients about their rights to informed consent? The incident also highlighted the need to have monitoring systems and also ensure funding to ethics committees so that they can do their work efficiently, said bioethicist Jillian Gardner of the Steve Biko Centre for Bioethics at the University of the Witwatersrand, South Africa.

Charles Mkoka, Christina Scott. Unauthorised HIV trial questions ethics processes. Scidev.net, January 29, 2009

Recruiting Indians in clinical trials: easy and cost effective

A study of 500 clinical trials involving drugs by the 20 largest US based pharmaceutical companies suggests that companies are conducting tests in countries like India for drugs that would have a market primarily in the West. One-third of these trials had *all* their sites outside the US. More than half of all trial sites for these trials were located outside the US.

"It appears many companies are testing drugs in countries where they do not intend to sell them. This creates serious ethical concerns," said Seth Glickman, a co-author of the study and assistant professor at the Duke Clinical Research Institute.

There are other ethical concerns as well, about conducting such trials in low income or developing countries like India. Local review procedures may be inadequate. Participants may give consent to participate in a trial because they receive treatment that they could otherwise not obtain. The drugs tested in India may not be available at an affordable price. There is also a possibility that less educated and poor people get recruited in such trials. The low costs and large patient population in countries like India and China continue to attract drug companies conducting these trials.

GS Mudur. India's sick turn West's guinea pigs. *The Telegraph*, February 20, 2009

Ethics of trials in developing countries

As western drug companies increase the proportion of clinical trial sites in low income countries, there is a growing concern that trials here may not meet ethical standards and good clinical practice norms.

According to a strategy paper by the European Medicines Agency (EMEA), "There is growing concern both among regulators and in public debate about how well these trials are conducted from an ethical and scientific/organisational standpoint and about the available framework for the supervision of these trials."

The EMEA has been monitoring the geographic origins of patients included in pivotal trials submitted in marketing authorisation applications between 2005 and 2008. It found that 25% of patients in these trials came from Latin America, Asia, the Commonwealth of Independent States and Africa.

SCRIP World Pharmaceutical News UK, February 18, 2009

Kidney rackets: vendors become touts

The touts who do the dirty work of the kidney trade are often poor people who have sold one kidney and now make money getting others to do the same thing. Three of six people arrested in a Kolkata-based racket in February turned out to be vendors who were hired to recruit more "donors". They had sold a kidney for up to Rs 1 lakh but as little as Rs 10,000 and a cell phone. Now they lure people with even smaller promises: luxury goods, food for a fortnight before and after the surgery. The touts were caught after they brought a potential vendor to the hospital on the pretext of offering him a job. When he was abruptly asked to undergo a blood test, he sensed that something was odd and sounded an alarm which led to the arrests.

Price of a kidney: Rs 10,000 & phone. *The Telegraph*, February 11, 2009

No more kidney trade in Chennai?

M Sekar is a rangoli powder vendor in Bharathi Nagar in Villivakkam where the residents are mostly construction workers and hawkers and every other household in the area has a donor. In December 2008, Sekar went public with the information that he sold one of his kidneys in order to repay

his debts and marry off his two sisters. Only, he wasn't given all the money promised.

T Santhakumar, president of the NGO Manitha Urimai Makkal Iyakkam that highlighted Sekar's story, said that this was just the tip of the iceberg.

Government officials have stated that an investigation into the allegation has ruled out the possibility of any new kidney racket; the kidney trade in the state is a thing of the past.

However, according to data from the Directorate of Medical Education in Tamil Nadu, 75% of kidneys available for transplants in Tamil Nadu are from live unrelated donors "by reason of affection or attachment towards the recipient", as per Clause 9 of Chapter II of the Transplantation of Human Organs Act (THOA). 27% of the recipients have been foreigners. The authorisation committees rejected only 18 out of 682 applications that appeared before it during 2007 and 2008.

A series of measures were taken to tighten the procedures relating to organ transplantation by issuing seven government orders from January 8 to September 5, 2008. Still, the sale of kidneys goes on and hospitals play ball because they need the business.

It is estimated that around 50% of the nearly 5,000 kidneys transplanted in a year in the country are donated by genuine live relatives, while the remaining 50% are "commercial kidneys". 1.5 lakh people in the country require dialysis or a kidney transplant every year. One in every 1,000 persons suffers from chronic kidney disease.

S Dorairaj. Organ trade: thriving market. *Frontline*, February 28-March 13, 2009

Private hospitals in Assam to provide emergency care

The Assam health and family welfare minister Himanta Biswas Sarma announced plans to pass a law requiring private hospitals to provide emergency services free of cost, without considering the patient's ability to pay. Such care should be provided for at least 24 hours after the patient enters the hospital. The announcement followed recent reports that private hospitals had been refusing emergency medical services to patients who could not afford to pay.

Sarma stated that the legislation would penalise hospitals which refused care to accident victims and others needing emergency services; if a patient who was refused care died, the hospital's licence would be cancelled. A similar law is already in place in Andhra Pradesh.

Private hospitals have denied that they refuse free emergency service.

Assam mulls emergency medical care law. *The Telegraph*, November 7, 2008

The state of health in India

The Voluntary Health Association of India's 2008 Report of the Independent Commission on Development and Health in India (ICDHI) highlights sharp regional imbalances in healthcare across the country.

At one end are Kerala, Maharashtra, Himachal Pradesh and Tamil Nadu with 18.8% of the population and health indicators like developed middle-income countries such as Venezuela, Argentina and Saudi Arabia. At the other end of the spectrum are the BIMARU-plus States (Bihar, Jharkhand, Madhya Pradesh, Rajasthan, Uttar Pradesh, Orissa and Assam) with 42% of the population and indicators close to those for sub-Saharan Africa and other low-income countries such as Sudan, Nigeria and Myanmar.

In 2001-02, public health spending as a percentage of total health expenditure ranged from Rs 84 per capita in Uttar Pradesh to Rs 836 per capita in Mizoram but not a single major state achieved the basic threshold level of Rs 500 per capita public health spending. There are only 0.6 allopathic doctors per 1,000 population and they are concentrated in the South and in more developed states and in urban and peri-urban areas. The four southern states have 63% of the colleges and 67% of the seats.

The ICDHI report cites National Sample Survey Organisation data to show that in Bihar and Uttar Pradesh more than one-third of those who were hospitalised fell into poverty on account of medical expenditure. Urban hospitalisation costs increased by 126% between 1995-96 and 2003-04; rural hospitalisation costs increased by 78%. In general, one-fifth of the population that is just above the poverty line will automatically slip into poverty if they face even one serious health crisis.

Jayati Ghosh. Failing health. *Frontline,* February 14-27, 2009

Patients' rights and the National Health Bill, 2009

The union health ministry has drafted legislation to regulate both the public and private healthcare systems. The National Health Bill, 2009, is meant to be a comprehensive legislation covering common problems that patients face including over-billing, refusal to release medical records and unexplained referrals to other hospitals. The bill would also make it mandatory for hospitals to appoint an independent forum, available round the clock, to address patient grievances. This forum would offer patients an alternative option to courts and other quasi judicial bodies such as the medical council.

The draft is the outcome of a long-standing demand by the Jan Swasthya Abhiyan (People's Health Movement). At present, patient's rights, such as the right to emergency care, are largely based on the interpretation of the law in various cases. The bill once passed would be all-encompassing.

Madhavi Rajadhyaksha. New bill to empower patients against hospitals. *The Times of India*, March 2, 2009

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