

FROM THE PRESS

A complex issue

As a step towards tackling the problem of sex determination tests in the country, the central government has ordered the cancellation of the licenses of 93 doctors convicted under the Pre-Conception and Pre-Natal Diagnostic Techniques (PC and PNDT) Act, 1996.

The decline in the child sex ratio (age group 0-6) since the 1961 census continues unabated. According to 2011 census, it has reached an all-time low of 914 females per 1000 males. In the 2001 census, it was 927 females per 1000 males.

The central supervisory board, set up under the PC and PNDT Act, has now approved the proposal to ban ultrasound sonography machines outside hospital premises and do away with the provision that allows any experienced doctor with six months training to register an ultrasound facility. The ministry's move will now allow for only professional radiologists to set up ultrasound facilities, and only state government-approved institutes to offer training.

Meanwhile the health ministry has had little success in blocking websites that promote gender selection tests. Responding to the ministry's request to ban the websites, the communications and IT ministry has stated that "nothing much could be done with the websites hosted outside India." Search engines like Google and Yahoo! have given a token undertaking that they will "stop carrying advertisements and sponsored links on sex determination". The communications ministry has told the health ministry that "what is available on the internet on this particular issue cannot be treated as advertisement, but information." Their claim is that the PC and PNDT act is "only meant for India" and "they cannot regulate the websites hosted outside the country".

Meanwhile, UK Member of Parliament Virendra Sharma, on a recent visit to Jalandhar, revealed that a UK-based charity has evidence to prove that an increasing number of non-resident Indians are travelling to India for pre-natal sex determination and abortions using Indian clinical facilities. Sharma said the study by a UK charity Jeena had gathered sufficient evidence to prove that there was an increase in the incidence of sex selective abortion involving NRI families.

Teena Thacker, Womb sex test: centre hits web firewall, *The Asian Age*, January 21, 2012. Available from: www.asianage.com/india/womb-sex-test-centre-hits-web-firewall-857
Archana Jyoti, Sibal deaf to site ban plea, *Daily Pioneer*, January 28, 2012. Available from: <http://www.dailypioneer.com/nation/38489-sibal-deaf-to-site-ban-plea.html>?
Jasdeep Singh Malhotra, NRIs use Indian clinical facilities for female foeticide: UK MP, *Hindustan Times*, February 6, 2012. Available from: <http://www.hindustantimes.com/India-news/Punjab/NRIs-use-Indian-clinical-facilities-for-female-foeticide-UK-MP/Article1-807617.aspx>

Unethical trials abound

The Supreme Court has issued notice to the union health ministry and the Medical Council of India following a petition seeking a probe into illegal drug trials in the country.

The notices were issued following a petition by a non-governmental organisation, Swasthya Adhikar Manch, which pointed out various cases of illegal trials going on in the country and demanded immediate action. It alleged that multinational corporations were using contract research organisations for clinical trials of their drugs which are not even approved.

Indore, where the NGO is based, has recently been in the news for clinical trials of various medicines conducted on 233 patients seeking psychiatric treatment, apparently without following the necessary guidelines. The trials, exposed by a former resident doctor of MGM Medical College, Anand Rai, were conducted between January 2008 and October 2010.

Following a huge uproar over the trials and related deaths, 12 doctors, including six involved in the trials on mentally ill patients, were fined a meagre amount of Rs 5,000 each for ignoring the protocols. The doctors had apparently obtained the approval of independent ethics committees attached to private hospitals.

The Indore case is not an isolated one. Recently a 55-year-old tribal woman died in Bhavanikunta hamlet of Wardhannapeta mandal in Warangal district of Andhra Pradesh. She was among the 20 people from the hamlet who volunteered for drug trials on payment of Rs 10,000 each. Last year, a Hyderabad-based research firm allegedly conducted clinical trials on an anti-cancer drug at a multi-specialty hospital on poor people without their informed consent. When the irregularities were brought to light, the firm was punished by withdrawal of the permission granted for conducting the trials. But when it submitted a statement on "corrective" actions, it was once again granted permission to go ahead.

T K Rajalakshmi, Criminal trials, *Frontline*, January 28-February 10, 2012. Available from: <http://www.frontlineonnet.com/fl2902/stories/20120210290203300.htm>. J Venkatesan, Apex court issues notice to Centre on 'illegal drug trials', *The Hindu*, February 7, 2012. Available from: <http://www.thehindu.com/news/national/article2866585.ece>. Anant Singh, Supreme Court issues notices to Centre, MCI on drug trials, *Goindocal*, February 7, 2012 Available from: <http://goindocal.com/india-%BB-legal-supremecourt-issues-notices-to-centgo-3695.htm>. A Raju, Illiterate women lured secretly by clinical trial firms in Andhra Pradesh, *Pharmabiz*, February 3, 2012 Available from: <http://pharmabiz.com/NewsDetails.aspx?aid=67326&sid=1>

Clash over organ sharing

After allowing swapping of organs, the Centre is planning to set up an apex national organisation to procure and distribute human organs. Under the new National Organ Transplant Programme, the Union health ministry has decided to set up a National Organ Procurement and Distribution Organisation (NOPDO) at the Centre and 10 State Organ Procurement and Distribution Organisations.

The NOPDO aims to increase the availability of organs from cadaver donors, build capacity for retrieval of organs and transplantation, and provide post-transplant services to both the recipients and living donors. The intention is to bring all organ banks, both public and private, under the NOPDO.

Meanwhile, a Chennai city hospital's refusal to part with donor livers has cost two end-stage liver patients their lives. The hospital refused to part with donor livers even though the patients were flagged off with the state organ registry as emergencies. Instead, the hospital used them on their own patients who were apparently lower in the waiting list maintained by the registry.

Organs such as heart, lungs, kidneys, liver and eyes procured from brain dead patients are shared by a network of hospitals through the registry. The hospitals submit their list of patients in need of organ donations to the registry, but the list is yet to be centralised. Hospitals which procure the organs give them to their own patients, often at a high price.

There is a lack of rules defining organ sharing, complain transplant surgeons. A senior transplant surgeon at the hospital that refused to part with the organs defended their move by saying that their hospital went all out to encourage people to become donors. As a result they were far ahead of other hospitals, including government hospitals, in procuring donations. This justified their action of not parting with the organs but using it for their own patients.

But doctors at the other hospital where the patients died argued that it was unethical to draw boundaries during emergency situations. Meanwhile health officials believe a centralised registry would be a solution to these problems.

Pushpa Narayan, Tug of war over organs leaves two patients dead, *The Times of India*, February 11, 2012. Available from: http://articles.timesofindia.indiatimes.com/2012-02-11/chennai/31049572_1_organ-registry-j-amalorpavanathan-brain-dead-patients Kounteya Sinha, Soon, national body to procure, distribute organs, *The Times of India*, January 22, 2012. Available from: http://articles.timesofindia.indiatimes.com/2012-01-22/india/30652484_1_transplantation-organ-banks-human-organs

Ethics issues hold up organ transplant

A Chattisgarh family's attempts at transplanting a kidney from a sister, Sonia Vayklip (33), to her brother Deepak (29) were delayed due to two key issues being unresolved: the fitness of the donor and her capacity for informed consent.

Doctors at the Lilavati Hospital, Mumbai, felt that Sonia was mentally incapable of giving her informed consent to the transplant surgery. Another issue was raised by Dr Sujata Patwardhan of the Zonal Transplantation Coordination Centre. Dr Patwardhan's reported objection was that as Sonia, the donor, had several stones removed from one kidney, the chances of stones occurring in the second kidney were high and this would endanger her health. On the other side, those in favour asserted that there was a 100% tissue match between the siblings and a delay was not affordable. The matter was debated at length by the doctors and before the Mumbai High Court, where Justices Mohit Shah and Roshan Dalvi declared that Sonia was not mentally challenged, thus clearing the way for the transplant, which was carried out on February 24. Both patients are said to be stable and all concerned are keeping their fingers crossed.

Malathy Iyer and Rosy Sequeira, Siblings have kidney transplant, at last, *The Times of India* Mumbai edition, February 25, 2012. Available from: <http://timesofindia.indiatimes.com/city/mumbai/Siblings-have-kidney-transplant-at-last/articleshow/12026600.cms>

Airlines grounded on sensitivity index

The persistent callousness in the country towards the differently-abled has come up in several cases concerning airline passengers. This time it was Spice Jet, which off-loaded Jeeja Ghosh, who suffers from cerebral palsy. Ms Ghosh who has been felicitated for her work for the differently-abled was on her way to Goa on February 19, to be honoured at a conference. After boarding the plane, she was told on the instructions of the pilot, to get off; apparently on the ground that the airline staff believed she was a "mental patient".

In another case the very next day, Anjalee Agarwal, who suffers from limb girdle muscular dystrophy which progressively restricts movement and confines sufferers to a wheelchair, was refused a wheelchair to get off a Jet Konnect flight from Delhi to Raipur. Further she was asked to sign an indemnity bond after boarding the flight. Then she was forced to agree to being manually lifted by male loaders, under threat of being flown back to Delhi if she failed to 'cooperate'. She was also told by the staff that she had failed to request a wheelchair, although she had done so while booking her ticket online.

This occurred though both passengers are leading activists of NGOs for the disabled, and are well-informed about their rights. Guidelines on the carriage by air of persons with disability or reduced mobility, framed by the Director General of Civil Aviation, prevent airlines from refusing to carry disabled passengers, and also provide for online booking of tickets.

Now, both airlines have promised to retrain their staff in sensitivity towards the differently-abled. The matter has also been taken up by Mukul Wasnik, union social justice minister, with the civil aviation minister. Wasnik has demanded a probe and strict action against those responsible, as also installation of 'ambu- lifts' in aircraft to facilitate the movement of

differently-abled passengers. He said this is required by rule and also asked for sensitisation of airline staff towards the disabled.

PTI. Jet accused of mistreating disabled woman, probe ordered. *The Statesman*, February 24, 2012. Available from: http://www.thestatesman.net/index.php?option=com_content&view=article&id=401174&catid=36 PTI, Off-loading of woman passenger: inquiry sought, *Zeenews.com*, February 22, 2012. Available from: http://zeenews.india.com/news/nation/off-loading-of-woman-passenger-inquiry-sought_759909.html PTI, Lack of info on cerebral palsy led to woman's offloading: *Spice, IBNLive.in.com*, February 24, 2012. Available from: <http://ibnlive.in.com/generalnewsfeed/news/lack-of-info-on-cerebral-palsy-led-to-womans-offloadingspice/967086.html>

Cut- price babies

Two *Mid-day* reporters, Bhupen Patel and Shubha Shetty-Saha, posing as a childless couple, exposed a baby-selling ring near Mumbai. The gang is said to be working out of an orphanage for disabled children in the suburb of Ulhasnagar and the contact persons for the racket are a staff member at a surrogacy centre in Mulund and a cook at the orphanage. During the sting operation, a six-day-old boy was sold to the 'couple' for Rs 2.30 lakh.

The racket is a boon for desperate couples eager to circumvent the lengthy procedures of the official adoption process. No documentation appears to be necessary, other than some proof of identity to give it a semblance of legality. The racketeers even provide a 'birth certificate' with the customers' names on it.

The babies are predictably the children of poverty-stricken couples who, the agents claim, have been persuaded to avoid an abortion to make a fast buck. Even so, the parents have little idea of the pickings which are pocketed by the agents. An added service offered by the gang is surrogacy, with the surrogate mother having sex with the customer and bearing a child. The whole low-tech operation is said to have been offered at about Rs 10 lakh.

The Child Welfare Committee and the state minister for women and child welfare promised strict action against the gang. However, all four accused were released on bail of Rs 1500 each, even before particulars of other children traded by them could be traced.

Bhupen Patel, Samarth Moray. Miscarriage of justice? Baby sellers let off on Rs 1,500 bail, *Mid-Day.com*, February 25, 2012. Available from: <http://www.mid-day.com/news/2012/feb/250212-mumbai-Miscarriage-of-justice-Baby-sellers-let-off-on-Rs-1-500-bail.htm>. *Mid-Day.com*, In Mumbai, buy a baby boy in seven days for 2 lakhs, *NDTV.com*, February 20, 2012. Available from: <http://www.ndtv.com/article/cities/in-mumbai-buy-a-baby-boy-in-seven-days-for-2-lakhs-177877?pfrom=home-otherstories&cp&cp> Correspondent, Baby bazaar gets minister's attention, *Midday.com* February 20, 2012. Available from: <http://www.>

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Clinical trials on the anvil for AYUSH drugs

Clinical trials are being made mandatory under a circular issued by the department of AYUSH for all current and new ayurvedic medicinal products in India. Guidelines for the purpose have already been issued by the authorities, and are to be implemented from April this year. They are based on the Central Drugs Standard Control Organisation's document on good clinical practices for pharmaceutical products. According to the draft, these guidelines should be followed for carrying out research in all Ayurveda, Siddha and Unani (ASU) and traditional medicines (TM) in India at all stages of development. Currently, clinical trials on ASU and TM medicines are reportedly being conducted by a few companies and institutions according to their own standards, based on Ayurvedic principles. The government's guidelines suggest extensive safety evaluation procedures for approval of ASU medicines including sub-chronic toxicity tests, genotoxicity studies and clinical trials. The demand for Ayurvedic and other traditional systems of treatment has been growing internationally. At the same time, importing countries want documented proof of the safety and efficacy of these drugs. Currently, raw materials with no assurance of uniform quality are obtained from varied sources, and this could affect product efficacy.

As the industry is chiefly in the unorganised sector, with small units across the country, this has made standardisation in quality a challenge. For years, these units have resisted the introduction of any regulatory reforms. The guidelines have been objected to by the Ayurvedic Medicine Manufacturers Organisation of India on the ground that the manufacturers have always complied with the Drugs and Cosmetics Act, 1945; hence no further trials are necessary. Two other concerns of the organisation are that multinational companies may enter and monopolise the industry, and foreign patients may be frightened off. It is therefore demanding more consultations with the government before the new rules are finalised.

P A Francis, GCP for ayurvedic drugs, *Pharmabiz.com*, February 1, 2012. Available from: <http://pharmabiz.com/ArticleDetails.aspx?aid=67294&sid=3> AMMOI to protest against proposed GCP guidelines for ASU drugs, *Ayurbhishak.wordpress.com*, January 3, 2012. Available from: <http://ayurbhishak.wordpress.com/2012/01/03/ammoi-to-protest-against-proposed-gcp-guidelines-for-asu-drugs/> Pharmaquest, Ministry specifies evaluation rules for ASU and traditional medicines, *Pharmaquest.biz*, January 20, 2009. Available from: <http://www.pharmaquest.biz/Policy-and-Regulations/Notification/Ministry-specifies-evaluation-rules-for-ASU-and-traditional-medicines.html>

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