Correspondence

Psycho-socio-economic stress as a risk factor for preterm labour: A community-based, case–control study from rural South India

Preterm birth is defined as birth before 37 completed weeks of gestation.[1] In India, the incidence of preterm birth has been reported to be 14.5%.[2] Preterm birth is a public health problem because it is associated with high perinatal morbidity and mortality, long term neurodevelopmental disabilities and poor respiratory outcome.[1] Maternal stress due to pregnancy-related anxiety, stressful life events, death of spouse, depression during pregnancy and poor self-esteem are risk factors for preterm labour.[3] Levels of stress for a pregnant woman are likely to be much higher in resource-poor settings such as India. We aimed to investigate whether psychosocial distress during pregnancy was associated with preterm delivery in the Indian sociocultural context.

This case–control study was done at the Department of Community Health, Christian Medical College, Vellore, which has a comprehensive community health programme for 50 years with annual census data, computerized health database, tiered organization of field health workers with weekly village clinics and a strong base hospital support.[4] Babies born with congenital anomalies and those born of multi-foetal pregnancy were excluded.

Cases were women who delivered preterm (n=24) and controls were those who delivered after 37 weeks (n=40) and matched for village of residence. The details of childbirth such as birth weight, gestational age at birth and antenatal complications were obtained from the hospital database. Information regarding exposure to stress and violence at any point during the pregnancy was collected by a masked personal interview in the postpartum period. To minimize the risk of recall bias, women who had delivered within 6 months of the interview date were chosen for the study. Elements from a previously validated standard stressful life events questionnaire were chosen on the basis of their relevance to the Indian context.[5] Responders rated some of the elements of stress on a scale of 1 to 10, where 1 was the least stressful and 10 the most. Table I shows the odds ratios and confidence intervals of the risk factors. After adjustment for age, parity, any hospitalization during pregnancy and medical complications such as anaemia, fever, pre-eclampsia and premature rupture of membranes, the stress factors such as a troubled relationship with in-laws (3.86; 95% CI: 1.10–13.59), habits of the husband such as alcohol abuse, smoking, extramarital relationships (3.40; 95% CI: 1.02–11.31), debts in the family (4.60; 95% CI: 1.26–16.86) and intimate partner violence (9.61; 95% CI: 2.63–35.14) emerged as significant. When these four factors were analysed in a backward conditional logistic regression model, intimate partner violence was a significant psychosocial risk factor (8.27; 95% CI: 2.41–28.42).

After adjustment for background issues such as husband's alcohol abuse, substance abuse and extramarital relationship, intimate partner violence in itself was a significant risk factor for preterm labour. Psychosocial stress factors are unique to different cultural and social scenarios. Therefore, a study of association between psychosocial stress and preterm labour needs to be adapted to regional and cultural specifics. Stress in itself being a subjective experience is difficult to measure by quantitative methods and so an attempt to overcome this limitation was made by introducing a stress scale to measure perceived stress. Physicians should routinely assess stress and intimate partner violence during antenatal care.

REFERENCES

1 Reedy NJ. Born too soon: The continuing challenge of preterm labor and birth in the United States. *J Midwifery Womens Health* 2007;**52:**281–90.

TABLE I. Psychosocial risk factors for preterm labour

Risk factor	Cases (n=24)	Controls (n=40)	Odds ratio (OR)	95% CI	Adjusted OR	95% CI
Age (<21 years)	3 (12.5)	4 (10)	1.286	0.26–6.31	1.063	0.34–3.31
Parity (primigravida)	14 (58.3)	16 (40)	2.1	0.75–5.88	2.447	0.72–8.34
Medical complications (anaemia, pre-eclampsia fever, premature rupture of membranes)	5 (20.8)	2 (5)	5	0.89–28.20	1.158	0.09–15.05
Hospitalizations during pregnancy	5 (20.8)	1 (2.5)	10.263	1.12–94.11	13.344	0.72–247.92
Mother's education <10 years	17 (79.8)	18 (45)	2.968	1.01–8.73	2.964	0.95–9.21
Employment status	5 (20.8)	9 (22.5)	0.906	0.26–3.11	0.700	0.18–2.72
Sleep <8 hours per day	10 (41.6)	10 (25)	2.143	0.73–6.32	2.666	0.79–8.96
Household work ≥4 hours per day	14 (58.3)	22 (55)	1.145	0.41–3.19	1.402	0.45–4.34
Husband's employment temporary	16 (66.7)	28 (70)	0.857	0.29–2.54	0.796	0.24–2.68
Husband working outside village	5 (20.8)	5 (12.5)	1.842	0.47–7.17	2.501	0.60–10.45
Family income <Rs 3000	12 (50)	17 (42.5)	1.353	0.49–3.74	1.144	0.38–3.46
Food insecurity	7 (29.1)	5 (12.5)	2.882	0.80–10.43	1.706	0.41–7.08
Poor health status of children	9 (37.5)	5 (12.5)	4.2	1.20–14.65	2.510	0.61–10.38
Concern regarding sex of the baby	13 (54.16)	17 (42.5)	1.599	0.58–4.43	2.533	0.76–8.50
Accidents or illness in the family	6 (25)	4 (10)	3	0.75–12.00	2.853	0.66–12.29
Troubled relationship with in-laws	10 (41.6)	7 (17.5)	3.367	1.07–10.64	3.863	1.10–13.59
Husband's alcohol abuse	13 (54.16)	17 (42.5)	1.599	0.58–4.43	2.101	0.68–6.46
Husband's smoking habit	11 (45.8)	21 (52.5)	0.766	0.28–2.11	1.134	0.34–3.82
Husband's habits (including smoking, alcohol, extramarital affair)	11 (45.8)	10 (25)	2.538	0.87–7.42	3.398	1.02–11.31
Debts in the family	13 (54.1)	12 (30)	2.758	0.965–7.878	4.599	1.255–16.858
Intimate partner violence	13 (54.1)	5 (12.5)	8.237	2.408–28.416	9.612	2.629–35.136

Values in parentheses are percentages

2 WHO Collaborating Centre for Training and Research in Newborn Care. *National Neonatal Perinatal Database Network. National Neonatal Perinatal–Database Report 2002–2003. National Neonatology Forum NNPD Network, India 2005*, p. 13.
3 Orr ST, Reiter JP, Blazer DG, James SA. Maternal prenatal pregnancy-related anxiety and spontaneous preterm birth in Baltimore, Maryland. *Psychosom Med* 2007;**69:**566–70. Epub 2007 Jul 16.
4 Joseph A, Joseph KS, Kamaraj K. Use of computers in primary health care. *Int J Health Sci* 1991;**2:**93–101.
5 Bergman K, Sarkar P, O'Connor TG, Modi N, Glover V. Maternal stress during pregnancy predicts cognitive ability and fearfulness in infancy. *J Am Acad Child Adolesc Psychiatry* 2007;**46:**1454–63.

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Cobblestone streets of Paris: Remembering Professor H. D. Tandon

Some years after I had left the Department of Pathology at the All India Institute of Medical Sciences (AIIMS), I chanced upon a passage in a book that described how the great Rudolf Virchow, appropriately attired and about to leave for a formal dinner, had to unexpectedly perform an autopsy, and how even after doing the autopsy, his dress remained as impeccable as before. Remembering how very particular Dr Tandon had always been about the meticulousness with which we conducted autopsies, as indeed all that we did, I photocopied the passage and posted it along with New Year greetings (it was the first week of January) to Dr Tandon. His letter of 18 January 1988, which I preserved, says a lot about him. I quote: 'It is evident from the passage that Virchow's attention to sartorial detail and the impeccable care he took of his attire was only a reflection of the same importance he attached to these attributes in the performance of the techniques of his studies. It has been my belief also that as a reverse, sloppiness reflects a general attitude of mind and is likely to reflect equally in all your activities, be they related to matters sartorial or scientific. How true, indeed, it is that a drop in your technical standards is apt to lead to an inexorable fall in the quality of your work.'

This was how the residency programme at the pathology department, AIIMS was run. Dr Tandon, one among the stalwarts who had painstakingly established the finest infrastructure and work culture, would have it no other way. For us residents, it was a gauntlet that had to be run.

For many of us, particularly those not from AIIMS, the early days in the department could be somewhat unsettling. This was not in the least made easy by the stern demeanour of Dr Tandon, who headed the team whose task it was to discipline us, *the natives,* as one of the American Jesuits in a Catholic school used to humorously put it! It took a while to realize that much caring went into all that appeared initially unpalatable.

The residents' manual that Dr Tandon had prepared for us, and perhaps the only one of its kind in AIIMS, was a virtual Rosetta Stone. It also made great reading, except that it had a few, at the time incomprehensible, French phrases thrown in! We were told of a certain histopathology pattern that Dr Tandon had so graphically and lovingly likened to the cobblestone streets of Paris! Since most of us had not seen Paris at that time, we opted to settle for the histopathology part, drab though it was compared to things French!

There was more to Dr Tandon than met the eye. When one of his students suffered severe burns he comforted her, weeks later when they met, as only a father can, with the words, 'You still look so beautiful!' That was the real Dr H. D. Tandon—stern carapace disguising a heart of molten gold!

This was not the only incident. In those days, when we used to have external lamps for microscopy, it was not uncommon for some of us to use lamps that had no plug tops and we would insert naked wires into the plug points. We knew this was unsafe, but the only danger we were worried about was that Dr Tandon might catch us doing it! One day, he did. The fault was mine, but in my absence the senior resident to whom the lamp belonged was summoned to his office—not a happy prospect. There was no firing, no stern gaze. Just the words, 'I do this for the safety of my boys!'

Dr Tandon was a thorough gentleman and an outstanding teacher, whom a student would like to reminisce about with fondness and warmth. His remembrance as a teacher and human being has not surprisingly been immortalized by one of his former students, a professor in Boston, with the institution in 2001 of a Dr H.D. Tandon International Fellowship in Dermatopathology at Boston University.

Remembering Dr Tandon for me has been a trip down memory lane and brings to mind the 3 years I spent in the pathology department of AIIMS. We were lucky to have seen people like him and some others who moulded us and gave us so much. Paying a tribute to him is paying a tribute to the noble profession of teaching. I am sure for many of us, his memory will never fade.

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Subjective versus objective debate

This refers to the letter 'Medical Council of India internal assessment system in undergraduate medical education' by Tongia.[1] It appears that Dr Tongia has not read the Medical Council of India (MCI) rules and our earlier paper[2] in the proper perspective. Here are some clarifications:

1. The MCI has not allotted 10 or 40 marks as written in the letter. MCI has only given 20% of the marks to internal assessment (IA) and, to the best of our knowledge, this is applicable to all colleges affiliated to the MCI.
2. In our paper on IA,[2] we had converted the marks to 100 for ease of understanding. However, for both theory and practical the proportion of IA continues to be as stated above.

It is undisputed that assessment guides learning and what is not assessed is not learnt. From that perspective, it is in keeping with

good assessment practices that the inclusion of soft learning areas in the marking scheme has been suggested. Translated to actual practice, assessment of attitude would mean only 4 marks out of 100 and not 40, as mentioned by Dr Tongia.

If we have to use IA in the same manner as term-end university examinations, then there is no need for IA. It has been introduced because it allows us to test a number of skills and competencies which cannot be tested by conventional examinations. The two test different competencies and are not mutually exclusive. If we cannot test a skill in an objective way, it does not mean that we should ignore that skill. Clinical competence includes a number of areas which do not allow objective assessment and leaving out those areas will be a serious setback to our efforts towards developing competent physicians.[3]

The debate on assessment is not *subjective versus objective*—it used to be a favourite topic in the 1970s though. The contemporary consideration is how to make assessment reliable. Since the 1990s, enough literature has accumulated to show that the reliability of subjective and less structured assessments can be as high as, or sometimes even higher, than that of highly structured objective assessments.[4] We have provided enough literature[2] to argue that objectivity is not synonymous with reliability. If we were to give a question paper containing only 5 multiple choice questions (MCQs) at the end of the MB,BS course, the results would be highly objective but they would not be a reliable measure of the student's knowledge. Similarly, if we made a wrong checklist for an objective structured clinical examination (OSCE) station by mistake, the results would be objective but not reliable. Objectivity only means that everyone will mark it the same way—it does not mean that the interpretation will be reliable. Vleuten *et al*.[4] have rightly contended that the misplaced pursuit of objectivity can lead us away from reliability and validity, the two essential qualities of any assessment.

REFERENCES

1 Tongia SK. MCI internal assessment system in undergraduate medical education system. *Natl Med J India* 2010;**23:**46.
2 Singh T, Anshu. Internal assessment revisited. *Natl Med J India* 2009;**22:**82–4.
3 Norman G. Non cognitive factors in health sciences education: From the clinic floor to the cutting room floor. *Adv Health Sci Educ Theory Pract* 2010;**15:**1–8.
4 Vander Vleuten CPM, Norman GR, De Graaff E. Pitfalls in the pursuit of objectivity: Issues of reliability. *Med Educ* 1991;**25:**110–18.

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Organ donation for transplantation: Hurdles imposed by thoughtless officials

On the whole, it has been very satisfying to be a part of the organ donation programme in our hospital. However, there are times when I wonder whether I should be enthusiastic about it at all.

It is depressing, for example, when in a series, the well-informed relatives of brain dead patients refuse organ donation despite detailed explanations from us. However, this is compensated for by the inspiration one feels when, quite unexpectedly, the illiterate relative of a poor patient readily agrees to donate organs and many lives change.

There are other problems as well. When the option of organ donation is put forth, some relatives question the integrity of our hospital. Some families want to be financially rewarded by the recipients of their patient's organs. We have learnt to take these things in our stride, albeit with difficulty.

What about the problems created by an agency that is supposed to help society, namely the police? Recently, we had a patient who suffered a severe head injury in a traffic accident and was transferred from a peripheral hospital. Deterioration in the neurological state to coma and inadequate ventilation prompted the referral. The patient came with an endotracheal tube and was breathing with the aid of a ventilator. Most of his brainstem reflexes were absent. The neurosurgeon decided against surgery as the prognosis was hopeless. The patient was declared brain dead just before midnight. On the morning of the next day, the relatives of the deceased pleasantly surprised us by agreeing to donate the patient's organs. I say pleasantly surprised because the family was from a very low socioeconomic background and the concept of brain death must have been difficult for them to comprehend.

We called up the appropriate police station as we were dealing with a medicolegal case. The policeman came after 3–4 hours and started interrogating the relatives in the intensive care unit, where we were busy preparing the patient for organ donation. At this stage, the policeman decided that as the patient was a victim of a traffic accident, he would not permit us to remove organs.

It took me and our social worker considerable time and effort to explain the concept of brain death and organ donation before the policeman reluctantly agreed to consider allowing us to proceed with organ retrieval. He contacted his senior (a Deputy Commissioner of Police) who stated that we would be allowed to retrieve the organs only after the postmortem examination. I felt that he was perhaps unaware of the concept of organ transplantation and the need for rapid retrieval of organs, so I volunteered to explain things to him. Though he seemed to understand everything I said, he insisted that the post-mortem had to be done first. I tried to explain that many brain dead patients are victims of traffic accidents and that the families of many such patients had donated their organs without difficulty. He was in no mood to verify the facts. The police officer who had come for enquiry seemed to understand the situation but could not convince his superior.

In the meanwhile, we called the Zonal Transplant Committee chief with a request for help. As we were losing precious time, I requested the police officer to connect me to the Assistant Commissioner of Police (ACP). I explained to the ACP that if the postmortem was done first, all the organs would be destroyed, and assured him that we would provide a detailed report on how the organs were retrieved. I did feel that I had convinced him. The Zonal Transplant Committee chief also spoke to senior police officials. Even so it took another hour to get the sanction. Finally, close to midnight the next day (almost 24 hours later), the patient was transferred to the operation theatre for organ retrieval. Would it not have been a shame if the brain dead patient had a cardiac arrest before organ retrieval?

I then informed the police station that they could proceed with their formalities. To convey this, I had to go through 4 persons at the police station who kept passing the phone to each other. It was only after I lost my temper over the phone that they agreed to act.

On the morning of the next day, the relatives came in late, saying that the medical officer who was to perform the mandatory postmortem had delayed them. By the afternoon, we had completed our formalities. However, this was not the end of the story. That night I got a telephone call from the person who had done the postmortem asking me who had given us permission for organ retrieval and demanding photocopies of all the documents in our hospital pertaining to the patient. We had already given him a summary of the events and copies of the operation notes. He was suspicious of medical negligence. We provided him all the documents he demanded.

Ultimately, the relatives got the body of their patient close to

midnight of the second day (almost 48 hours after the patient was declared brain dead). Will the family ever recommend that, in a similar situation, their friends or relatives should be willing to donate the organs of their loved ones?

We need to take every possible step to make the process of organ donation smooth and minimize mental trauma for grieving relatives. This will encourage many more to take this noble step. If postmortem examination is mandatory in accident cases, can the rule books not make provision for the exceptional circumstance where organ retrieval takes priority over such examination? Would it not be easier if the person conducting the postmortem examination could be present in the operation theatre at the time of retrieval of the organs and conduct the assessment in the hospital soon after the organs have been removed to save valuable time and enable rapid handing over of the body to the grieving relatives?

The concept of organ donation is poorly understood and not widely accepted in our society. As medical personnel, it is our duty to educate and encourage individuals and families to come forward to save the lives of others through the donation of vital organs. Greater still is our responsibility as a community to pave the path for a difficult final step.

Certainly, imposing hurdles—as in the case of the patient described here—will only deter well-meaning persons and set back the organ donation programme.

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Death penalty to Kasab: Time to revisit the role of health professionals in capital punishment in India

A special trial court in Mumbai on 6 May 2010 sentenced the lone surviving gunman from the November 2008 attack in Mumbai (commonly referred to as the 26/11 attacks), Mohammed Ajmal Amir Kasab, to 'be hanged by his neck until he is dead'. The case has been fairly high-profile and has attracted much media and public interest because of the gruesome nature of the attacks, which shut down the financial capital of the country and led to the loss of many lives. Understandably, the decision has been welcomed widely in India and there have been calls for carrying out the execution swiftly. However, as part of the normal legal procedure in such cases under Section 366 of the Criminal Procedure Code, the sentence will need ratification by the Bombay High Court. In the case of ratification by the High Court, Kasab's defence team can approach the Supreme Court to appeal the sentence, and further file an appeal for Presidential mercy. This means that the follow up of the case could take time, unless the authorities push to fast-track the process.

The heightened attention related to the case has brought capital punishment to the fore of public consciousness again. News channels and the print media focused on the lack of trained and experienced hangmen who could carry out the hanging,[1] and several volunteers who were willing to play the role stepped forward. It is surprising that the associated issue of the presence of a physician during the hanging has not been deliberated in the media. This is perhaps because the involvement of the physician does not seem prima facie to be as direct as that of the hangman.

The role of medical personnel in the enforcement of the death penalty has been discussed in academic literature in the past, including in this Journal.[2] To summarize, a doctor(s) is involved in evaluating an inmate's fitness for execution, is present during the hanging and certifies death. This role is usually ascribed to the jail physician, and directly conflicts with his/her role as the physician of the inmate. It violates one of the foremost duties of a physician: *primum non nocere* (first, do no harm). If the mode of execution is changed from hanging to lethal injection, as recommended by the Law Commission of India[3] in 2003, physicians and allied healthcare personnel will play a greater role than in capital punishment by hanging, as they would need to administer the lethal cocktail of drugs.

The participation of medical personnel in the enforcement of the death penalty is morally troubling and also goes against the professional tenets of medical practice. The World Medical Association has consistently opposed the participation of physicians in capital punishment.[4] The patient's interest always scores over any other consideration, including duty to the employer (the State, in the case of medical personnel employed in the jail system). Healthcare personnel in India should oppose the involvement of their peers employed in jails in implementing the death penalty, and lobby with the government in this regard.

Just as healthcare personnel should not participate in torture, even if it is of enemy combatants, they should also refrain from playing any kind of role (passive or active) in administering capital punishment. Upholding professional ethics and the best interests of patients should be the primary and sacrosanct duty of a healthcare professional and trump any other considerations.

REFERENCES

1 Press Trust of India. Kasab gets death, but where is the hangman? *The Times of India*. Available at *http://ibnlive.in.com/news/kasab-gets-death-but-where-is-the-hangman/114725-3.html?from=tn* (accessed on 15 May 2010).
2 Bhan A. Killing for the state: death penalty and the medical profession: A call for action in India. *Natl Med J India* 2005;**18:**205–8.
3 The Law Commission of India. 187th report on Mode of Execution of Death Sentence and Incidental Matters. 2003. Available at *http://lawcommissionofindia.nic.in/reports/187th%20report.pdf* (accessed on 15 May 2010).
4 The World Medical Association. WMA Resolution on Physician Participation in Capital Punishment. *Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981and amended by the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 and the WMA General Assembly, Seoul, Korea, October 2008. Available at http://www.wma.net/en/30publications/10policies/c1/index.html* (accessed on 15 May 2010).

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Clinical Trials Registry–India: Raising the veil

The Clinical Trials Registry–India (CTRI), an online system for registering clinical trials being conducted in India, was launched on 20 July 2007.[1] In the initial 6 months, the CTRI registered only 11 trials. Since then, more than 800 trials have been registered. In 2 years, this initiative has moved from being a voluntary one to a mandatory requirement.

In February 2008, a statement issued by the editors of 11 major biomedical journals helped provide a boost to the initiative.[2] Also, the World Medical Association, in its revision of the Declaration of

Helsinki, now specifies that 'every clinical trial must be registered in a publicly accessible database before recruitment of the first subject'.[3] In November 2008, the Drugs Controller General of India (DCGI) started 'advising' all those applying to the DCGI for permission to conduct clinical trials to register their trials.[4] However, the DCGI's decision to make it mandatory for trials initiated after 15 June 2009 to be registered has provided the maximum support to the initiative in India.

The CTRI had registered 298 trials in 23 months before 15 June 2009, while 551 trials were registered in the following 9 months. Most of the new trials being registered are from the pharmaceutical industry. We hope to focus our attention next on registering the clinical trials conducted in various medical colleges, including those conducted as a part of postgraduate dissertation. We also hope to enlist the support of institutional ethics committees as they are ideally placed to make it mandatory to register all clinical trials.[5]

The CTRI provides, for the first time in India, a public record of clinical trials being conducted in the country that is freely available to all. This mechanism allows a complete record of trials, irrespective of whether they are published or not, to be available to any researcher. Registering of clinical trials is likely to have a positive impact on the quality of research too.

Lower costs, a less stringent regulatory environment and a large drug market have been proposed as reasons for the 'globalization' of clinical trials. A recent report indicates that one-third of trials (157 of 509) and a majority of study sites (13 521 of 24 206) are outside the USA.[6] Many of these trials are being conducted in developing countries.[7] There is justifiable concern among the Indian regulatory authorities that 'global multicentre trials' are a front and a majority of patients are recruited from India, which raises ethical concerns. Global trials registered with the CTRI are required to declare the number of patients proposed to be recruited from India under the brief summary of the dataset.

As part of the routine verification and validation process, trial registrants are required to submit Ethics Committee (EC) approval documents. This has revealed the lack of awareness of various regulatory processes, especially those related to ethical review of all human research. Instances where academic institutions did not have a proper EC to review clinical trials were also brought to our notice. We hope that exposure to the public eye, including the scientific community, would help improve the processes involved in research in India.

One of the objectives of a clinical trial registry is to empower the lay public and offer patients the choice of enrolling in a clinical trial to gain access to the latest breakthrough treatment options. This is especially true in cases of life-threatening conditions such as cancer. Registries in the developed countries are widely utilized by the lay public for such a purpose. At the CTRI, too, we have begun to receive such queries from the lay public.

The CTRI functions as a database for clinical trials and does not have any regulatory authority. However, through analyses of the data collected, we may help India remain a favoured destination for clinical trials, without compromising on standards of patient safety.

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REFERENCES

1 Pandey A, Aggarwal AR, Seth SD, Maulik, M, Bano R. Juneja A. Clinical Trials Registry–India: Redefining the conduct of clinical trials. *Indian J Cancer* 2008;**45:** 79–82.
2 Satyanarayana K, Sharma A, Parikh P, Vijayan VK, Sahu DK, Nayak BK, *et al*. Statement on publishing clinical trials in Indian biomedical journals. *Natl Med J India* 2008;**21:**105–6.
3 World Medical Association (WMA). Declaration of Helsinki. Ethical principles for medical research involving human subjects. 59th WMA General Assembly, Seoul, October 2008. Available at *http://www.wma.net/en/30publications/10policies/b3/index.html* (accessed on 10 March 2010).
4 Pandey A, Aggarwal A, Maulik M, Seth SD. Clinical trial registration gains momentum in India. *Indian J Med Res* 2009;**130:**85–6.
5 Ethical Guidelines for Biomedical Research on Human Participants. Available at *http://icmr.nic.in/ethical_guidelines.pdf* (accessed on 10 March 2010).
6 Truelove C. 21st Annual Report: Belt tightens on big pharma. *Med Ad News* 2007;**26:**4–7.
7 Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, *et al*. Ethical and scientific implications of the globalization of clinical research. *N Engl J Med* 2009;**360:**816–23.

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