CORRESPONDENCE

Made in India? Ethics of outsourcing surrogate motherhood to India

Outsourcing is a commonly used word today. Corporations outsource many of their functions and processes to developing countries, especially India, to cut costs and improve efficiency. Clinical trials were thus outsourced to India, and now it appears that children are being produced by outsourcing surrogate motherhood to India. Consequently, a new and unique enterprise known as "reproductive outsourcing" (also called "reproductive tourism") is a rapidly expanding business in India (1, 2).

Many couples living in western countries use Indian surrogate mothers to bear their genetically related children (3). The reason for using Indian surrogate mothers is obvious: the cost comes to about $25,000, roughly a third of the price in the United States. That includes the medical procedures, payment to the surrogate mother, air tickets and hotel costs for two trips to India–one for the fertilisation and a second to collect the baby (1).

Every married couple has a right to have a child and we should not scorn the couple that turns to a surrogate mother. But the very process of outsourcing surrogate motherhood involves many issues and these needs to be addressed while endorsing or limiting the procedure.

***Exploitation of women*:** The requirement of a surrogate mother for the procedure raises some apprehensions about the exploitation of women. The couple who want the child has to find a surrogate mother themselves or they can take the help of a law firm or semen bank to do so. These firms can advertise for surrogate mothers (4).

In the Indian context, the involvement of touts in "seeking business" cannot be ruled out, and the touts may employ dubious methods in this search. So, the question is, "Is it ethical to find a surrogate mother in this way?"

It is possible that due to poverty or some other reason, family members may compel a woman to act as a surrogate mother. The women who enrol for such procedures are mainly from a poor socio-economic background. The surrogate mother is paid by the couple who want the child, and it is possible that the mother may not be adequately paid.

The guidelines published by the Indian Council of Medical Research (4) provide for an agreement between the surrogate mother and the couple desiring the child regarding payment. But, since we are dealing with often illiterate and powerless women, the agreement may not be a fair one. The mandatory clauses that are to be included in the agreement are not spelt out nor is any specific format provided in the guidelines. In the absence of such a requirement, clauses favourable to the couple and not the surrogate mother may be incorporated.

Ethics of the procedure: The government is actively promoting India as a medical tourism destination, but the exchange of money for babies is making many people uncomfortable. There are no reliable statistics on how many surrogate births are being arranged in India for foreigners, but anecdotal evidence suggests a sharp increase (1). Surfing the internet, I have found many sites advertising the services of clinics. Is it ethical for medical practitioners to advertise in this manner?

The conditions or circumstances in which the surrogate mothers are kept in the clinics also warrant consideration. In Anand, a city in Gujarat where the practice was pioneered in India, more than 50 surrogate mothers are pregnant with the children of couples from the United States, Britain and elsewhere. Fifteen of them live together in a hostel attached to a clinic (1). The women are literally being kept in custody. Such practices violate basic human rights. In addition, these women may suffer mental anguish since the doctor ensures that they don't bond with the babies by constantly reminding them that the foetuses they are carrying are not theirs (2).

It is possible that even basic procedures such as informed consent of the mother may not be taken, or may be obtained in a questionable manner. Also, considering the money involved, the mother may not be inclined to ask the doctor about the dangers or risks involved in the pregnancy. Money seems to be a crucial factor for many surrogates.

Another important issue that needs attention is what sort of protection would be given to the mother in case of prenatal or postnatal complications, or if death occurs. If continuing with the pregnancy endangers her life, is the mother entitled to terminate her pregnancy?

***Interests of the child*:** Other issues that need to be addressed include what to do with the child if the couple does not return to India to claim it, or refuses to take the child for some reason, or the couple dies or they divorce.

What happens if the child is born retarded or physically challenged? Neither the surrogate mother nor the putative parents may want such a baby. Legally, if the couple refuses to accept the child, the surrogate mother and her husband are obliged to keep the child since it is she who has given birth to the child. In divorce cases, who would be entitled to the custody of the child? These questions need considerable thought and maybe the agreement between the surrogate mother and the couple should address these concerns.

The phenomenal increase in surrogate pregnancies makes it essential that these issues be properly addressed. Regulation that addresses these ethical and other issues will ensure that parenthood is achieved with dignity and not at the expense of any of the people involved.

***Rajesh Bardale**, Lecturer, Department of Forensic Medicine, Government Medical College and Hospital, Nagpur INDIA e-mail: Bardalerv@yahoo.com*

References

1. Gentleman A. India nurtures business of surrogate motherhood. *The New York Times.* 2008 Mar. [cited 2008 Dec 15]. Available from: http://www.nytimes.com/12008/03/10/world/asia/10surrogate.html

2. Ramchandran S. India's new outsourcing business - wombs. *Online Asia Times* 2006 Jun. [cited 2008 Dec 15]. Available from: http://www.atimes.com/atimes/south_asia/hf16df03.html
3. Johnston J. The ethics of outsourcing motherhood to India. *Medscape J Med* 2008; 10: 52 [cited 2008 Dec 15]. Available from: http://www.pubmedcentral.nih.gov
4. Indian Council of Medical Research and National Academy of Medical Sciences. National guidelines for accreditation, supervision and regulation of ART clinics in India. [cited 2008 Dec 15]. Available from: http://www.icmr.nic.in/art/art_clinics.htm

Responding to deaths during a clinical trial

The deaths of patients during clinical trials conducted by the All India Institute of Medical Science (AIIMS), New Delhi, revealed under the Right to Information Act (RTI), made news in most leading newspapers in India (1,2,3,4,5). The government has asked for a high level enquiry into the deaths (2,4) which may help in re-establishing public trust in ethical research. In the interest of continuing medical research, some issues such as questioning the authenticity of ethically approved clinical trials and the use of the RTI Act need further discussion.

The ethical conduct of a clinical trial does not end with the formulation of a study design and obtaining a signature on an informed consent form. Fatal adverse experiences for subjects in clinical trials should be scrutinised. But, certainly, there are difficulties in establishing the cause of death when interpreting the data retrospectively. It is not easy to attribute risk of death to the trial drug/vaccine, and it is even more difficult to rule out its possible contribution.

Other confounding factors may play a vital role in determining the final outcome. Increased mortality may be attributed to the natural course of diseases such as encephalitis, Gaucher disease, or advanced HIV/AIDS in the study populations that are generally associated with poor outcome. In such circumstances, it is highly probable that the control arm might have a higher death rate than the treatment arm. Also, we should consider the mortality rate among all subjects under trial instead of the absolute number of deaths. In a large study, this number may not have much impact when compared to the natural outcome of the diseases. In addition, death rates in the trial may be compared with the rates achieved in other similar reported clinical trials in order to rule out any causal relationship of the trial drug with mortality.

It is ethical to involve infants in trials provided there is minimal risk, which is defined as no more risk than can be expected in the normal protected environment of the child (6). If it is found that the hypothesis on which the trial is based is beneficial, at least half the subjects in a randomised controlled trial may benefit while those in the control arm will be no worse off than if the research had not been done (7).

However, any breach in ethical conduct of a clinical trial should always be evaluated. New rules for clinical trials were implemented in 2005 (8) probably due to the demand from multinational drug companies and organisations. It has become easier and more cost-effective for western countries to conduct clinical trials in India rather than in their own countries, which have strict regulations, complicated safety and compensation requirements and a smaller study population.

India's vast genetically diverse population with plentiful research subjects, its favourable economic conditions, cheap labour and low infrastructure costs have accelerated the process (8,9). In addition, a considerable number of trials are industry-sponsored trials of pre-approval therapies which are largely focused on defining indications and marketing strategies. Hence, it becomes of utmost importance to protect the most vulnerable subjects in a trial. At the same time, it is difficult to judge what constitutes sufficient grounds for disqualifying a research investigator from conducting human experiments.

The Randomised Control Trial (RCT), begun in the mid-20th century, probably ranks as one of the most important milestones in the history of medicine. It is because of RCTs conducted over many decades that we are able to use a wide variety of safe drugs today. They are among the most reproducible and valid forms of research and rely on randomisation and unbiased evaluation of outcomes (based on placebo controls and "hard outcomes" such as patient death) to minimise errors (10). RCTs usually have built-in safeguards and external oversights and audits, all of which protect against serious biases.

Both doctors and patients are aware that no drug is free of adverse effects. Safety and adverse effects are inversely related to each other. The degree of balance between the two determines further acceptability for human use. We believe that most reputable clinical trials investigators, particularly in government academic institutions, are careful to ensure the integrity and credibility of their work. Moreover, to the best of our knowledge, there are virtually no studies which have derived information prospectively in individuals who have died during clinical trials.

Interrogating honest investigators who are primarily interested in expanding knowledge and research may result in undue stress, leading to their refusal to conduct future trials. We must protect patients enrolled in clinical trials, but we must find better ways to protect professionals also. If we do not, the progress of medical research in India may come to a standstill, particularly in controversial and distressing areas (11).

Prasanta Raghab Mohapatra, Deepak Aggarwal*, Department of Pulmonary Medicine, Government Medical College and Hospital, Chandigarh INDIA e-mail: prmohapatra@hotmail.com, drdeepak@hotmail.com*

References

1. Sinha K. 49 babies die during clinical trials at AIIMS. *The Times of India* 2008 Aug 18. [cited 2008 Sep 6]. Available from: http://timesofindia.indiatimes.com/India/49_babies_die_during_clinical_trials_at_AIIMS/rssarticleshow/3374492.cms
2. Prakash S. NGO urges human rights body to probe infant deaths at AIIMS. *Hindustan Times* 2008 Aug 25. [cited 2008 Sep 6]. Available from: http://hindustantimes.com/StoryPage/Print.aspx?Id=e259ca41-2c96-480c-afaf-56e22ec62f3f.
3. RTI India. 49 babies died during clinical trials at AIIMS in last 30 months. 2008 Aug 17. [cited 2008 Sep 6]. Available from: http://www.rtiindia.org/forum/6212-49-babies-died-during-clinical-trials-aiims-last-30-months.html

4. Inquiry on into death of 49 kids, AIIMS says tragedy wasn't due to new drugs' trial. *Indian Express* 2008 Aug 19. [cited 2008 Sep 6]. Available from: http://www.indianexpress.com/story/350390.html
5. Door Darshan India: Drugs used in clinical trials safe: AIIMS. [cited 2008 Sep 6]. Available from: http://www.ddinews.gov.in/National/National+-+Other+Stories/dsdsf.htm
6. Redmon RB. How children can be respected as 'ends' yet still be used as subjects in non-therapeutic research. *J Med Ethics* 1986; 12: 77-82.
7. Smyth RL, Weindling A M. Research in children: ethical and scientific aspects. *Lancet* 1999 Sep; 354: SII21-SII24.
8. Nundy S, Gulhati CM. A new colonialism? Conducting clinical trials in India. *N Engl J Med* 2005 Apr 21;352(16):1633-6
9. Shuchman M. Commercializing clinical trials--risks and benefits of the CRO boom. *N Engl J Med* 2007 Oct 4;357(14):1365-8.
10. Yusuf S, Collins R, Peto R. Why do we need some large, simple randomized trials? *Stats Med* 1984 Oct-Dec; 3(4):409-22
11. Craft AW, McIntosh N. Southall and colleagues vindicated once more. *Lancet* 2006 Apr1;367(9516):1080-5.