

CONTROVERSY

Stem cell transplantation in India: tall claims, questionable ethics: a response

SAMUEL JK ABRAHAM

Director, Nichi-In Centre for Regenerative Medicine, Chennai, Tamil Nadu INDIA email: sam@surg2.jp

This is with reference to the article titled "Stem cell transplantation in India: tall claims, questionable ethics" (1).

As the director of Nichi-In Centre for Regenerative Medicine, Chennai, I would like to state that the use of the term "unethical" to refer to our institute is unjustified considering our credentials, conduct and values; further, it has been used without any verification or communication with us on what exactly we have been doing.

1. I would like to refer to the Indian Council of Medical Research's (ICMR's) national guidelines on stem cell research and therapy published by the ICMR and available online (2). The guidelines state, in clause 13, that stem cell therapy for everything except bone marrow transplantation should be done with the approval of an institutional ethics committee or Institutional Committee for Stem Cell Research and Therapy (IC-SCRT). Further, Directorate Controller General of India is necessary for marketable products. It is unfortunate that the above guidelines of the ICMR have not been cited as a reference in the article. It is only based on these guidelines that one can say whether one is ethical or not.

(i) Till date Nichi-In has been following the above guidelines strictly and ours would have probably been the first institute to have informed the IC-SCRT apart from the Institutional Ethics Committee (IEC).

(ii) Though the National Accreditation Committee for Stem Cell Research and Therapy (NAC-SCRT) mentioned in the ICMR guidelines has not yet been formed, and even though the guidelines do not state that the IEC/IC-SCRT meeting proceedings should be reported to the ICMR, Nichi-In has been regularly sending the proceedings of the IEC/IC-SCRT to the ICMR without fail. This demonstrates our willingness to be transparent and our commitment to adhere to the guidelines and follow ethical principles.

(iii) Though it is not mandatory, we invited the ICMR expert team to visit us. The team visited us on May 7, 2007 and went through our credentials including our protocols and publications. The team consisted of Dr SS Agarwal, Dr Dipika Mohanty, Dr PB Seshagiri and Dr Geeta Jotwani.

(iv) All our research and clinical work is presented in meetings such as those organised by the Indian

International Society for Stem Cell Research (ISSCR). Though there are no stem cell research forums in our country we are conducting regular annual meetings. We have been taking the pain to organise an annual symposium every October since our first in October 2006. At this symposium, all our work is presented to a gathering of physicians and scientists moderated by experts from the ICMR as well as eminent people from clinical and research arenas outside our collaboration.

(v) Though the GMP/GTP for cell processing/stem cell research guidelines have not been published in the above mentioned ICMR guidelines, we have been following the best protocols to see that cleanliness, sterility, particle count, equipment calibration, entry procedures, etc are maintained as required for cell culture procedures.

2. As far as the relationship between us and the hospital(s) that avail of our services is concerned, I would like to stress the following matters of concern:

(i) We get approval from the head of the hospital saying that their ethics committee has approved the clinical study. We also sign a memorandum of understanding demarcating the responsibility between us and the hospital. In all such applications the relevant physicians are the principal investigators and handle the patients after obtaining their informed consent.

(ii) We do not advertise and we never send any of our personnel to any hospital for marketing. We do not encourage, support or provide our cell processing expertise for clinical indications other than those which have evidence of such usage in peer-reviewed publications.

(iii) When we asked the visiting ICMR expert team about our responsibility when a non-GCP (Good Clinical Practice)-compliant hospital wants to avail of our services, they replied that we were responsible until the specimens leave our premises; after this, the responsibility is with the hospital (the present GCP guidelines in India do not require a laminar air flow system that is mandatory for an operation theatre in which when cells packed in a Class 100 environment is opened, contamination cannot be ruled out).

3. Nichi-In has been working with several institutes on research using stem cells/progenitor including the Institute of Pathology of the ICMR where we have been working on finding solutions to several diseases prevalent among the lower socioeconomic sections of the country such as persistent corneal ulcers, burns etc. We do this as a commitment to society with an aim of developing cost effective remedies; we want to see that these newer technologies should not remain accessible only to the affluent. The unjustifiable remarks made in the article will only dampen the spirits of people like us who have

been working on projects that will help the masses in the country.

If the publications relevant to the various applications of bone marrow stem cells are required, we can send the same in hard copy to your postal address.

References

1. Pandya SK. Stem cell transplantation in India: tall claims, questionable ethics. *Indian J Med Ethics* 2008; 5: 16-8.
2. Indian Council of Medical Research. *National guidelines on stemcell research and therapy*. [cited 2008 Mar 31]. Available from: http://www.icmr.nic.in/stem_cell/stem_cell_guidelines.pdf

Reply to: Stem cell transplantation in India: tall claims, questionable ethics: a response

SUNIL K PANDYA

Department of neurosurgery, Jaslok Hospital and Research Centre, Mumbai 400 026 INDIA email: shunil3@gmail.com

Professor Dr R Narayanan and Dr M Balasubramaniam, experts at Life Line Hospital, have informed me that the hospital has deputed Dr Samuel Abraham to discuss my essay on their behalf.

I offer comments on points made by Dr Samuel JK Abraham, Director, Nichi-In Centre for Regenerative Medicine (NCRM) Chennai (1). I have reproduced Dr Abraham's observations and preface each of my comments with my initials - SKP.

1. Point raised by Dr Abraham: ICMR issued national guidelines on stem cell research and therapy.

SKP: In my published essay I have noted: "Even on Christmas Day, 2007, the ICMR draft guidelines on the use of stem cells, cleared by the law ministry, await cabinet approval." I have also noted that till this is done, they will remain open to debate and open disregard. In support of this I quoted Dorairajan Balasubramanian, research director at the LV Prasad Eye Institute in Hyderabad, himself involved in the use of stem cell to treat eye diseases. "Guidelines are only guidelines. Any violations cannot be punished."

2. Point raised by Dr Abraham: "Though it is not mandatory, we invited the ICMR expert team to visit us. The team visited us on May 7, 2007 and went through our credentials including our protocols and publications. The team consisted of Dr SS Agarwal, Dr Dipika Mohanty, Dr PB Seshagiri and Dr Geeta Jotwani."

SKP: We have an unequivocal statement from Dr Vasantha Muthuswamy, senior deputy director-general at the Indian Council for Medical Research (ICMR): "We have not given any approval to Lifeline Hospital." She elaborated: "ICMR has not given recognition to any centre for clinical applications. The only centres which we have cleared for basic research on stem cell biology [are] Manipal Acunova at Bangalore and Niche in

stem cell research and regenerative medicine at Chennai."

The approval granted by ICMR was only for basic research and this was granted only to Niche and not to Lifeline Hospital.

Dr Abraham does not refer to this at all. We do not have the report issued by the ICMR team, which is said to have visited Lifeline Hospital nor the team's conclusions or recommendations. ICMR's decision on the report of this committee should be of considerable interest to all of us.

The web site of Lifeline Hospital clearly states: "All stem cell trials in Life Line Hospital are registered with NIH, USA and ICMR, India."

Dr Muthuswamy's unequivocal statement above clearly shows that this is not so as regards the ICMR.

The National Institutes of Health (2) and the International Stem Cell Forum (3) do not refer to Life Line Hospital in any of its panels on stem cell research.

I am unable to confirm from any source that Life Line Hospital stem cell trials are indeed registered with NIH, USA and ICMR, India. Certainly, they do not appear to have approved such trials.

Dr Abraham has avoided dealing with this unverifiable statement on Life Line Hospital's web site.

3. Point raised by Dr Abraham

"(iv) All our research and clinical work is presented in meetings such as those organised by the Indian ISSCR. Though there are no stem cell research forums in our country we are conducting regular annual meetings. We have been taking the pain to organise an annual symposium every October since our first in October 2006. At this symposium, all our work is presented to