

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

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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

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.”

SKP: The issue is not one of good practices. It is much more fundamental. What gives independent institutions the authority to use stem cells to cure heart disease, spinal cord damage, liver failure and cancer on patients and advertise such usage on the internet and perhaps through other media?

Surely, laboratory research into such uses of stem cells, success in animal experiments and long-term evaluation for well-recorded complications from stem cell research trials should precede clinical usage.

A diligent search of medical journals and study of the papers to which Life Line Hospital experts have referred in their emails to me show no publication on any such preclinical study by them.

As regards “taking the pain to organise an annual symposium every October” may I suggest that till such time as they document every aspect of their work in reputed, indexed journals, there is no way that independent scientists can assess their findings and conclusions.

As matters stand, desperate and gullible patients and their well-wishers will remain misguided by announcements made by such institutions as Life Line Hospitals on their web sites. Lacking any means for verification claims made on the web site, they may spend huge sums with questionable results and possible harm in the form of complications.

4. Point raised by Dr Abraham: 2. (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.”

SKP: If making announcements on the web site does not constitute advertising, I don't know what does.

How does one classify statements reproduced verbatim by me in my published essay from the website of Life Line Hospital in Chennai (such those on spinal cord damage) if not as an advertisement?

As regards peer-reviewed publications, all those sent to me by experts at Life Line Hospitals are from centres abroad. The lone publication from Life Line Hospital describing their work or results is entitled “Autologous stem cell injection for spinal cord injury - a clinical study from India.” I understand that it was published by Dr R Ravi Kumar, Dr S Narayanan and Dr Samuel Abraham in *Regenerative Medicine* in November 2007. (Volume 2, no 6, supplement). I cannot lay my hands on a copy of the full text so withhold my comments on it.

There is no publication from this hospital on the other diseases being treated at Life Line Hospital: heart disease, liver failure and cancer.

5. Point raised by Dr Abraham: “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 addresses.”

SKP: I strongly recommend that these publications - based on work done at Life Line Hospitals - be sent to the Editor of *Indian Journal of Medical Ethics* for scrutiny by Dr George Thomas and the editorial team and by any independent expert(s) the team chooses. An editorial analysis of these papers can then be published in the journal.

References

1. Abraham SJK. Stem cell transplantation in India: tall claims, questionable ethics: a response. *Indian J Med Ethics* 2008; 5: 84-5.
2. National Institutes of Health. Resources for stem cell research. Homepage on the internet. [cited 2008 Mar 31]. Available from: <http://stemcells.nih.gov/research/intlresearch.asp>
3. International Stem Cell Forum. Homepage on the internet. [cited 2008 Mar 31]. Available from: <http://www.stemcellforum.org/>