

## Only umbilical cord blood banking for stem cells permissible by the Indian Council of Medical Research: Perception of medical professionals

Stem cell (SC) banking aims to preserve the cells cryogenically to retain their dynamic SC nature when thawed.<sup>[1]</sup> In the National Guidelines for SC research, the Indian Council of Medical Research (ICMR) has stated that “Last decade has witnessed a proliferation of indiscriminate use of SC-based therapies without establishing either their safety or therapeutic efficacy, and has led to the exploitation of vulnerable patients. This has the risk of adversely affecting patients both in terms of their wellbeing and their economy.” The ICMR claims that no scientific evidence to substantiate clinical benefits with the use of SCs derived from different biological tissues other than umbilical cord blood (UCB) have been accumulated. Hence, the recent guidelines permit only UCB for the storage of SC to prevent premature marketing of unproven SC therapies and generate new scientific-based knowledge while addressing ethical concerns.<sup>[2]</sup> These recent guidelines may affect the scope of SC research in India and curb any potential breakthroughs, affecting medical science as a whole. Lahiry *et al.* have stated that more clarity about the implications of the recent guidelines should be taken from the administrative bodies.<sup>[3]</sup> Based on these facts, we have tried to assess the perception of medical professionals about the recent guidelines and their possible consequences.

Medical doctors and R&D professionals were invited to answer a survey questionnaire that was designed on a 5-point Likert scale after validating it on a small subset of population. The questionnaire consisted of participant information, followed by questions to assess their knowledge on various SC sources, SC therapy and its implications, and their perception of ICMR guidelines permitting only UCB for the storage of SC. The questionnaire was made available online using Google Forms and was circulated widely among the professional groups, and the responses obtained were extracted onto a Microsoft excel sheet. Manual feedback forms were collected from professionals who could not submit the responses online. The responses

were analyzed using IBM SPSS Statistics Version 25 Illinois, Chicago, USA.

The questionnaire was filled by 230 participants of various qualifications, with 40% representing the pre- and para-clinical departments and 60% representing the clinical departments. Among all the participants, 51% had 0–10, 14% had 10–20, and 5% had 20–30 year’s postgraduate (PG) experience and 30% were PG students. The perception of the participants was compared after grouping them based on their qualification, departments, and number of years’ of experience and no significant association was seen with Pearson’s Chi-square value >10, >30, and >5, respectively.

Out of the 230 participants, 94% agreed that the field of therapeutic medicine was benefitted by SC therapy; 68% believed that SC therapy was better than conventional therapy for the treatment of leukemia, aplastic anemia, degenerative disorders, etc.; and 85% opined that autologous SC therapy would provide treatment with minimal chances of rejection and other side effects. Nearly 67% of the participants believed that UCB-derived SC was more potent than SC from other sources. However, only 9% of the population felt that the use of umbilical cord tissue and bone marrow as sources for SCs was unethical.

Surprisingly, only 30% of the medical professionals who took part in the survey were aware of the changes in the ICMR guidelines for SC research. This may be because the new guidelines on SC have not reached all the medical professionals and researchers. Hence, a communication should be made by the ICMR to the heads of the institutes, insisting them to circulate it among all the medical professionals and researchers. Even though 37% agreed and 48% of the participants were neutral to the changes in the ICMR guidelines, over 60% of them agreed that the restriction on the storage of SC only from UCB reduces the resources available for future research. Of the study population, 67% of the participants agreed that stored SC would be better

utilized if the private profit-making laboratories are replaced by government/academic/nonprofit organizations; 37% were in favor of this restriction, sighting ethical issues and commercial implications. The banking of all kinds of SC for research purposes might help India produce alternate treatment methods for diseases such as acute lymphoblastic leukemia.<sup>[4]</sup> Hence, we can conclude that this issue still needs further scientific debate and scrutiny after effective communication of the guidelines has been made to reach every medical professional.

We could reach only a small number of medical doctors and R&D professionals.

The recent restriction on SC banking put forth by ICMR is not receiving adequate support from the medical fraternity. Considering that the implications of the restrictions are far-reaching in the medical field, the guidelines may have to be relooked and revised.

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### Conflicts of interest

There are no conflicts of interest. Anissa Ann Biju, Akila Prashant, Prashant Vishwanath, Shobha Chikkavaddaragudi Ramachandra

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