News from here and there

Call for toning down hype about stem cell research

In a press release in May 2016, the International Society for Stem Cell Research (ISSCR) published their updated guidelines for stem cell research and clinical translation. Originally formulated in 2006, the updated guidelines emphasize the need to maintain the integrity of research and research subjects while keeping patient welfare, transparency and social justice in the forefront. The ISSCR stated that it is the responsibility of all factions, who create public awareness about stem cell science and medicine in the general population, to present realistic expectations and provide accurate reports of progress and setbacks about the trials under research. This responsibility extends, but is not limited, to scientists, clinicians, pharmaceutical industries, science communicators and the media.

The statement comes at a time when the field of stem cell research is growing at a rapid pace for a variety of human diseases and disorders, and there is an increasing expectation in the public that these new therapies may provide relief and benefit to millions of people worldwide.

The categorical recommendation to downplay the hype that is often generated with 'promising' research trials has been included in ISSCR guidelines for the first time. Other first-timers in the guidelines include the need to define an embryo research oversight process (to clearly define both human embryonic stem cell and human embryo researches not explicitly pertaining to stem cells or to the generation of new stem cell lines) and a recognition of the need to establish comprehensive standards of evidence for preclinical and clinical phases of the research, as the clinical trial progresses, and to rigorously evaluate the results for safety and efficacy before approval for marketing is sought.

These guidelines are particularly relevant in India, where stem cell clinics have mushroomed in recent years.

Dr Olinda Timms (Adjunct Professor, Department of Health and Medical Humanities, St John's Research Institute, Bengaluru) said, 'The Guidelines for Stem cell Research and Clinical Translation released by the ISSCR in May 2016 are an attempt to update documents released earlier by the Society, and expand their scope to include more recent technologies in gene-editing and research on stem cells. The single document brings together the guidance from two earlier documents (Guidelines for the Conduct of Human Embryonic Stem Cell Research 2006, and Guidelines for the Clinical Translation of Stem Cells 2008), making it easier for researchers in this field, and reinforcing common principles of patient safety, social justice, transparency and research integrity that run through both sets of guidelines.'

The need for ethical oversight in human embryo research has been retained, as well as unmitigated caution in every stage of clinical research. The guidelines offer a comprehensive overview of research standards, patient protection and responsibility, especially in the area of public communication of scientific developments and possibilities. Among the new additions to the guidelines, generation of induced pluripotent (iPS) cells is exempt from stem cell research overview, gene-editing of nuclear genomes of human sperm, egg or embryo is supported, and principles for evaluating clinically applied research on mitochondrial replacement therapy is defined.

The Indian Council of Medical Research 'Guidelines for Stem Cell Research 2013' is the most recent iteration of the guidelines governing stem cell research in India and describes regulatory compliance and oversight for Indian researchers, as well as prohibited areas such as reproductive cloning and germ line gene therapy. The ICMR Ethical Guidelines for Biomedical Research on Human Participants, currently under review, also contain a section on stem cell research and its regulation.

The constant evolution of guidelines at both national and international levels is an indication of exciting new possibilities, but unknown risk of harm to all stakeholders in research. The much awaited clinical applications must not only be rigorously proven safe, but ethically sound, accessible and socially acceptable.

MAHARRA HUSSAIN, *Dubai, United Arab Emirates*

Resident doctors in Maharashtra to undergo mandatory mental health screening

Resident doctors, mostly in their twenties, are otherwise healthy persons. They, especially those in the clinical branches, put in long working hours. In recent times, work environment for the resident doctors is increasingly becoming stressful and hazardous. The combination of high stress and long working hours drives some of them to substance abuse in the form of alcohol drinking, tobacco smoking and has been observed to cause depression and suicidal tendency. An incident that occurred in October 2015, where three resident doctors of a hospital in Mumbai were arrested as they were found driving in an inebriated state, prompted the Maharashtra Association of Resident Doctors to request the state government for this provision of residents undergoing mental health screening. The Maharashtra University of Health Sciences passed a resolution in the last week of April 2016 stating that resident doctors will have to mandatorily undergo mental health screening and physical health check-up at the start of their residency programme, and an annual mental and physical health check-up thereafter. This move, the first time ever in India, is expected to help in identifying vulnerable persons and facilitate counselling for them.

Dr I.V. Rao, Former Vice-Chancellor, Dr N.T.R. University of Health Sciences, Andhra Pradesh said, 'Resident doctors especially postgraduate students have enormous workload to cope up with during the 3-year course. They are involved in patient care, at times working for 48–72 hours constantly, shouldering the entire burden of running the hospitals on their own. In addition, they have to study the subject of their specialty to acquire the necessary theoretical knowledge to perform well in examinations. They also have to do original research work to produce their dissertation. No wonder this culminates in enormous physical and mental strain on these young doctors with disastrous consequences in some cases. The violence against doctors by patients' relatives without reason has compounded the atmosphere of stress faced by the residents. Therefore, the decision of the Government of Maharashtra to introduce mandatory periodic physical and mental health check-up of resident doctors is welcome and justified. This would

certainly help to improve their confidence and morale for better living and improved health.'

Dr Prathap Tharyan (Professor of Psychiatry, Christian Medical College, Vellore) said, 'Studies done in India and elsewhere show that 30%–50% or more of residents suffer from the consequences of prolonged high job stress, such as burnout, depression, anxiety disorders, suicidal ideation, alcohol and substance misuse. These in turn are associated with an increased risk of committing medical errors. Acting on this knowledge to screen and identify vulnerable people is a welcome step. If this initiative is to succeed, some important issues that need to be addressed are: (i) mental health screening using self-administered screening instruments will need to be followed, in those with high scores on screening, by confirmatory interviews by trained mental health professionals. Adequate numbers of such trained personnel are needed, who are skilled in providing counselling, problem-solving, stress management, etc. as well as in using psycho-pharmacological agents judiciously, and only if appropriate; and (ii) ensuring confidentiality is crucial, as is the need to ensure that this screening process is not used to discriminate against those identified with high stress or its consequences. This should ideally stimulate further initiatives from an organizational perspective to address working hours and working conditions, and to reduce job stress and burnout and increase job satisfaction in all healthcare establishments and across all levels of healthcare providers in India. However, it may require legislation to ensure this.'

ALLADI MOHAN, *Tirupati, Andhra Pradesh*

Supreme Court asks MCI to formulate procedures for medical college inspection

On 6 May 2016, a Supreme Court bench comprising Justices M.B. Lokur and N.V. Ramana directed the Medical Council of India (MCI) to consult the Central Government and prepare a standard operating procedure (SOP) for inspection of medical colleges as required under the MCI Establishment of Medical College Regulations, 1999.

The Court stated that the SOP should be completed within 6 weeks and be accessible on the MCI website. It said that to introduce transparency and accountability in medical colleges, the inspection team's report should be displayed on the websites of both the concerned medical college and the MCI so that potential students know what to expect.

The bench termed the state of medical colleges in India as rotten and imposed a penalty of ₹5 million on the Bhubaneswar-based Kalinga Institute of Medical Sciences (KIMS) for arbitrarily raising the number of MBBS seats from 100 to 150 in an academic year and playing with the future of the students.

The bench further stated that the ministries concerned in the Government of India (GOI) need to be far more proactive in ensuring that medical colleges have all the necessary facilities, clinical materials, teaching faculty, accommodation, etc.; otherwise the health of the citizens of our country will take a beating in coming years due to inadequately educated doctors.

The events that led to the SC judgment are as follows: KIMS, a recognized medical college, was eligible to admit 100 students to the MBBS course every year. In 2014–15, it was given permission to admit an additional 50 students (total 150 students). In January 2015, a MCI inspection team carried out an assessment and found several serious deficiencies. The MCI then recommended to the GOI to deny permission to KIMS to add another 50 MBBS seats. In June 2015, the GOI sent a communication to KIMS asking the institute not to admit the additional 50 students for the academic year 2015–16.

KIMS challenged the same in the High Court of Odisha. Subsequently the court directed the GOI to give provisional permission to KIMS to conduct the course for the additional 50 students during 2015–16. The High Court said that this was an interim order. Pursuant to this order, the GOI granted interim permission to KIMS to increase the MBBS student intake from 100 to 150 for the academic year 2015–16, subject to certain conditions.

KIMS admitted 50 more students for the MBBS course for the academic year 2015–16, thus increasing the strength from 100 to 150.

The Supreme Court in October 2015, on an appeal by the MCI, ordered that status quo be maintained. In November 2015, the Supreme Court asked the High Court to hear the pending writ petition expeditiously. In December 2015, the High Court directed the MCI to send a fresh inspection team to KIMS. A report was to be submitted on or before 23 December 2015.

A MCI team carried out a fresh inspection of KIMS in January 2016 and again found a large number of deficiencies, which were then communicated to the GOI.

In March 2016, the High Court directed the MCI to grant necessary permission to KIMS to impart education to the enhanced number of students, observing that no deficiency as alleged existed in the present situation.

The Supreme Court made the following observations while disposing of the appeal filed before it by the MCI.

- The High Court should have been more careful while allowing admission of the extra number of students.
- The state of medical colleges in India is awful.
- Medical education is a very serious matter and if an expert body finds that the facilities of a medical college are insufficient, courts should not take a different view except for strong jurisdictional reasons.
- KIMS should not go scot-free as it ventured into adventurist litigation, thereby endangering the career of students.
- The MCI should prepare an SOP for conducting future inspections.

Dr Nobhojit Roy (Professor and Head of Surgical Services, Bhabha Atomic Research Centre Hospital, Mumbai) said, 'This is an archetypal case demonstrating the power and chaos within medical education in India. Clearly, matters can be only made worse by courts now getting into the fray. The Supreme Court did well to restore the authority of the MCI, as a regulatory body.'

P.M. NISCHAL, *Bengaluru, Karnataka*