News from here and there

Indian certification of medical devices scheme (ICMED) launched

Manufacturers of medical devices find it both time-consuming and costly to obtain globally accepted quality certification in India. To overcome these hurdles, Indian certification of medical devices (ICMED), country's first indigenously developed international class certification scheme and quality assurance system for medical devices manufactured in India, was launched in New Delhi on 15 March 2016. The ICMED scheme is an initiative of the Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB).

The scheme has been launched with two levels of certification: ICMED 9000 certification, which is ISO 9001 plus additional requirements; and ICMED 13485, which is ISO 13485 plus additional requirements. ICMED is considered to be a milestone for consumers as well as manufacturers. The scheme is expected to improve quality, enhance patient safety and eliminate trading of substandard products/devices.

Dr S. Ramakrishnan, Professor of Biomedical Engineering, Indian Institute of Technology-Madras, Chennai, told this *Journal:* '[It is]… interesting to note this initiative by AIMED and QCI. Such formal training and exposure would enable Indian medical device manufacturers to enhance the quality of their products and processes, boost their confidence to try out innovative devices and to make their presence felt in the international market. This attempt is timely and absolutely essential to address the increasing complexities in the medical device industry. As a staunch advocate of regulations, standards and calibrations of medical devices, I welcome this initiative.'

ALLADI MOHAN, *Tirupati, Andhra Pradesh*

Parliamentary Committee Report on the functioning of Medical Council of India

On 8 March 2016, the Standing Committee on Health and Family Welfare (the committee) under the chairmanship of Professor Ram Gopal Yadav submitted the ninety-second report entitled 'The functioning of Medical Council of India (MCI)' in both houses of the Indian Parliament. The committee took oral submissions from representatives of the Ministry of Health and Family Welfare and oral and written submissions from various experts and had discussions with various stakeholders and state governments. Forty-six memoranda were received by the committee. These were subsequently forwarded to the MCI, which however, did not submit its comments. Some observations and recommendations of the committee are:

1. *Health systems and challenges in the delivery of health services*: The advances in certain health parameters cannot hide India's failures in achieving the desired levels of healthcare delivery. India lags behind many developing countries on key health indicators, including maternal and child mortality. Sixty-three million Indians face poverty each year due to healthcare costs alone, clearly indicating that healthcare is prohibitive for people in general and the poor in particular. There is an acute shortage of doctors in India. The total number of doctors in India is much lesser than official figures (doctor–population ratio 1:1674) and may be closer to 1:2000. Also, there is skewed distribution of medical colleges, with around 65% concentrated in the South and West of the country. Six states with 31% population have 58% of the MBBS seats. The recommendations are that urgent measures must be taken to augment the number of doctors, both specialists and superspecialists. There must be better distribution of medical colleges and an increase of undergraduate and postgraduate seats. Each state should plan for an optimal doctor–population ratio of 1:1000.
2. *Constitution and composition of MCI*: The MCI has a disproportionate representation from the private sector and consists largely of doctors. Also, there is no limit on the reappointment of members to the council. The committee recommended that a regulatory mechanism be set up wherein the regulators are appointed through an independent and transparent selection process. Diversity must be brought in, to include other professionals such as public health experts, health economists, legal experts, quality assurance experts and patient advocacy groups. A member of the council should not have more than two terms in office.
3. *Undergraduate medical education*: There is a critical gap between the medical education system and the health system. The primary reason is that medical graduates mainly work and train in tertiary care settings, whereas the vast majority of patients go to small clinics and outpatient departments of small hospitals, and very few go to tertiary care centres. There is no evaluation of the standard of medical education. The curriculum is didactic, while the world has moved on to competency-based curricula. Further, medical education has failed to instil soft skills such as concern, courtesy and compassion. There is no streamlined and transparent admission process. The recommendations are to revamp the present system with the emphasis on training a holistic doctor with the essential skills. The postgraduate entrance examinations should be conducted immediately after the final MBBS examinations so that the graduate doctor can concentrate on practical skills during internship. Soft skills, including ethics, ought to be made one of the cornerstones of medical education. The government should immediately introduce the common medical entrance test after removing all likely roadblocks. This will ensure that merit becomes the criterion for admission. The ministry of health and family welfare should have a key role in regulating the fees across the country.
4. *Regulation of professional conduct of doctors*: While there are outstanding doctors with impeccable credentials, there are also many unprincipled medical professionals. The profession has not dealt with complaints in a transparent manner. The MCI Code of Ethics Regulations, 2002 is idealistic in nature with no apparatus in place to oversee its execution. The recommendations are to have a Code of Medical Ethics which

is well-defined and has a provision for transparency, with definite timelines. A proper appeal mechanism should be in place. Medical education and ethical conduct of medical practitioners should be separated so as to receive complete attention. A separate board of medical ethics needs to be set up on the lines of the United Kingdom General Medical Council and the Australian Medical Council.

Dr George Thomas (former editor, *Indian Journal of Medical Ethics*), told this *Journal:* 'The recommendations of the Parliamentary committee are good, but they are limited in scope. They do not address the basic question of what is expected from medical graduates in India. It would be useful to define what the goal of medical education in India is, and work backwards to establish a system that is likely to attain the goal.'

P.M. NISCHAL, *Bengaluru, Karnataka*

Canadian Health Minister announces legalization of marijuana

On 20 April 2016, Canadian Minister for Health, Dr Jane Philpott announced the legalization of marijuana at the United Nations General Assembly Special Session. Incidentally, this took place on the unofficial day of marijuana celebration, also known as '4/20'. Crowds were engaged in public demonstrations supporting widespread use of marijuana all across, with over 25 000 people celebrating in the city of Vancouver alone. The Canadian government cites legalization as a route to decrease criminal exploitation and drug trading, in conjunction with increased safety for children.

Philpott said this was to ensure that marijuana is kept out of the hands of children and profits out of the hands of criminals. Moreover, legalization has led to a standardized level of care and ability for government agencies to implement national frameworks to protect vulnerable populations, such as children and youth, in countries such as the USA. However, legalization also offers considerable financial benefit: government profits have ranged in the tens of millions of dollars from taxation of controlled marijuana alone. Finally, for those concerned over concordant crime, state crime did not increase in six US states post-legalization.

Preliminary studies show the majority of adults over 18 years of age smoke marijuana recreationally, with over half using inhaled methods and a smaller majority using edibles. Monitoring such habits will be crucial in the coming years to establish proper surveillance and public health planning. Standardization on delivery methods will be helpful as the inhaled form is faster-acting, with a shorter duration compared to the ingested format.

Physicians in Canada are also recognizing the possible utilities of marijuana. Dr Mateya Trinkaus, a medical oncologist at Markham-Stouffville Hospital, in Ontario, Canada told this *Journal*: 'Marijuana is an important adjunct for addressing the pain and symptoms (specifically low appetite, nausea, unwellness) that can occur with malignancy. We are routinely offering marijuana and have had some good success with its use.' Changes in use both medically and otherwise are coming to Canada within the next year. Longitudinal monitoring will need to be done to fully understand the associated health and public policy impacts this change will have in Canada.

SAMARPITA DAS, PRETTY VERMA and PAMELA LIAO, *Canada*

Economic survey reveals private hospitals cost four times as much as government healthcare facilities for treatment

A report by the National Sample Survey Organization was quoted in the Economic Survey 2015–16, which was tabled in Parliament in February 2016. It highlighted the differences in costs of treatment between private and government hospitals. This amounted to an increase in cost of up to four times in private hospitals as compared to government facilities, for all kinds of treatments, excluding childbirth, based on data collected between January and June 2014. When out-of-pocket expenses for childbirth were also considered, this difference increased ten-fold. The approximate cost for treatment per hospitalized case in private hospitals was ₹25 850 compared to ₹6120 in public healthcare facilities.

While acknowledging the expansion in the coverage provided by government-funded insurance schemes to 13.1% of rural and 12% of urban Indian populations, the report emphasized that the differences in expenditure posed a challenge to the provision of affordable and accessible healthcare to a majority of the population. It recommended that the government should prioritize expenditure in the healthcare sector to combat the lack of resources and meet increasing requirements. This would help in ensuring provision of accessible, affordable and equitable quality healthcare to the marginalized and vulnerable sections of the population. The report also recognized the contribution of private facilities in providing outpatient and hospital-based care to a large spectrum of the Indian population and suggested overcoming the shortage of human resources such as doctors, nurses and other medical personnel as a prerequisite for efficient and effective delivery of health services.

Dr Sunil Pandya (Emeritus editor, *Indian Journal of Medical Ethics*) told this *Journal*: 'Private hospitals are of two kinds: trust hospitals and for-profit hospitals. Trust hospitals were originally funded by the trust, which expected no returns. We now see trust hospitals subject to the pressures of a market economy. The trusts expect all expenses to be met from income generated from patients. For such a measure to succeed, each and every patient must pay the full cost incurred in … treatment. The wealthier patient is expected to generate an excess of funds that can be used to upgrade equipment and for other needs.'

He added: 'For-profit private hospitals use all possible means—fair and foul—to generate profit … huge purchases [of equipment and medicines] attract large discounts from manufacturers.... These discounts are not passed on to patients. Several hospitals exert overt pressure on consultants to ensure that all tests (laboratory, imaging, etc.) are done in these hospitals and nowhere else. Targets are also set. With such attitudes, costs are unlikely to be low. The person who must bear them is the patient.'

He further added: 'Higher costs [are] justified in private hospitals because they are not subsidized by government or any other public agency. It is unfortunate but true that private hospitals are much better staffed and equipped than are government hospitals. They must, therefore, find the means to meet their costs. The chief source has to be patients seeking care in these hospitals. It is the duty of government to provide healthcare of the highest quality to the poorest of our patients. To do so, it must have institutions staffed by individuals of unchallenged repute and integrity. Our national expenditure on healthcare is shameful and needs to be multiplied.'

MAHARRA HUSSAIN, *Dubai, United Arab Emirates*