News from here and there

Faulty medical devices

Medical devices, which are intended to heal and cure, may contribute to morbidity and mortality. A medical device is an 'instrument, apparatus, appliance, software, material, or other article' used for 'diagnostic or therapeutic purposes', as per the Medical Devices Rules, 2017. The medical devices industry in India accounts for 4%–5% of the total national US$ 96.7 billion healthcare market.

In 2010, Johnson and Johnson's Acetabular Hip Resurfacing System (ASR) implant was recalled globally because of metal poisoning, which resulted in a high rate of revision hip surgeries. Despite the global recall of this implant, the Central Drugs Standard Control Organization (CDSCO) in India cancelled its licence after 2 years in 2012, and a medical device alert was issued on the Johnson and Johnson ASR implants only in 2013. Moreover, only about 1200 of the 4700 people who had received the hip implant in India have been tracked so far.

Some commonly used medical devices are pacemakers, artificial knees, contraceptive devices and medical mesh implants. It is alarming that many of these devices are not subjected to clinical trials or are tested partially.

The International Consortium of Investigative Journalists (ICIJ) reported growing documentation of health scandals in India in recent years concerning medical devices. The investigation reveals many serious issues, including bribing of doctors by pharmaceutical companies to promote implants. Patients are made to undergo unnecessary operations, have faulty implants, revision surgeries, etc. because 'targets' are set for doctors (International Consortium of Investigative Journalists. The Implant Files. 2018 Nov 25. Available at *www.icij.org/investigations/implant-files*; [accessed on 21 Jan 2019]).

The monitoring for medical device injury started in 2014 from across 13 centres in India. Since then, there have been only14 cases of device recall as per the ICIJ. The Indian Pharmacopoeia Commission reports that there have been as many as 556 'medical device adverse events' in 2018, most of which were linked to coronary stents and orthopaedic implants.

In January 2013, the University of California, San Francisco and the Australian Joint Registry published a perspective in the *New England Journal of Medicine*, which elaborated on the complex history of how metal-on-metal hip implants were released to the public (Ardaugh BM, Graves SE, Redberg RF. The 510(k) ancestry of a metal-on-metal hip implant. *N Engl J Med* 2013;**368:**97–100). The loopholes in the clearance of 510(k) implants by the United States Food and Drug Administration enabled many devices to be sold by claiming 'substantial equivalence' or 'predicate devices', which meant that they were similar to already approved devices and could overcome the clinical trial barrier—even if the original device was voluntarily recalled by the manufacturer.

Healthcare regulations have been far from effective in India. More than 250 journalists around the world are working to reveal the hazardous immediate and after-effects of such medical devices. They are probing into the safety, efficacy, rational use and ethical implications of these devices. They are questioning manufacturers' responsibilities and the terms of compensation for any harm. The good news is that regulatory bodies have awakened. One example is the inclusion of stents in the National List of Essential Medicines with price control. In the case of Johnson and Johnson's faulty stents, the court has responded, though less forcefully, to the demands for compensation. A strong civil society movement is required to safeguard patients' rights.

JYOTI PRIYADARSHINI SHRIVASTAVA
Gwalior, Madhya Pradesh

Indian government launches new scheme for quality healthcare for all

The Ayushman Bharat Yojana (ABY, also called Pradhan Mantri Jan Arogya Yojana/National Health Protection Scheme [NHPS]) is a Central Government-sponsored scheme launched under the Ayushman Bharat Mission of the Ministry of Health and Family Welfare in India. The scheme was announced by Prime Minister Mr Narendra Modi in his Independence Day speech on 15 August 2018 and was formally launched on 23 September 2018.

ABY is a health insurance scheme for the 100 million economically weak and financially vulnerable families comprising approximately 500 million Indian citizens. The scheme, which will be one of the largest healthcare schemes in the world is intended to work at all levels right from primary healthcare centres to the tertiary care level. Under this scheme the performance of hospitals will be monitored and star ratings issued accordingly.

This scheme will cast a financial burden of ₹50 000 million in the coming financial year. The scheme offers health insurance worth ₹500 000 annually per family irrespective of the size of the family. The scheme aims to eventually establish 100 000 health and wellness centres all over the country. The policy provided will be a family floater type of insurance policy (where the limit of the insurance policy can be utilized by any family member) and the premium amount will be reasonable and fixed by state health agencies.

The scheme will be formed by absorbing many other health schemes such as the Rashtriya Swasthya Bima Yojana, Senior Citizen Health Insurance Scheme, Central Government Health Scheme, Employees' State Insurance Scheme, etc.

Eligibility of beneficiaries is decided by the lack of housing, meagre income and other deprivations in rural areas and on the basis of occupation in urban regions. Eligible families will be issued a health card by Ayushman Mitra (a youth employed under ABY in hospitals to operate the scheme, handle software, guide patients and keep patient records).

The key features of the scheme are that all its benefits will be portable throughout the country, meaning that a beneficiary covered under the scheme will be allowed to take cashless benefit from any public/private entitled hospital all across India; the entitlement to be enrolled in the scheme will be

decided on the basis of deprivation criteria in the Socioeconomic Caste Census 2011 database and, to control costs, the payment will be made on the basis of rates to be defined and decided by the government.

JYOTI PRIYADARSHINI SHRIVASTAVA
Gwalior, Madhya Pradesh

Infosys prize 2018 in life sciences awarded to Professor Roop Mallik

On 5 January 2019, the Infosys Science Foundation (ISF) honoured the winners of the Infosys Prize 2018 at an award ceremony in Bengaluru. This was the tenth year of the awards.

Individuals who have made momentous contributions in the fields of Engineering and Computer Science, Humanities, Life Sciences, Mathematical Sciences, Physical Sciences and Social Sciences are awarded this annual prize that includes a medal of pure gold, a citation and a prize amount of US$ 100 000 (or its equivalent in Indian Rupees). The award celebrates success in research and is a marker of excellence in these fields. The cash prize is tax-free for Indian citizens. The recipient of the Infosys Prize 2018 in Life Sciences was Professor Roop Mallik, Department of Biological Sciences, Tata Institute of Fundamental Research (TIFR), Mumbai.

The jury consisted of six outstanding academics—Professor Pradeep K. Khosla of the University of California (Engineering and Computer Science), Professor Amartya Sen of Harvard University (Humanities), Professor Mriganka Sur of Massachusetts Institute of Technology (Life Sciences), Professor Srinivasa S.R. Varadhan of New York University (Mathematical Sciences), Professor Shrinivas Kulkarni of California Institute of Technology (Physical Sciences) and Professor Kaushik Basu of Cornell University (Social Sciences), who selected the winners from 244 nominees.

Professor Roop Mallik was awarded the Life Sciences prize for his ground-breaking studies on molecular motor proteins, enzymes that power much of the movement in living organisms. He identified and measured the forces needed to transport large particles within cells, and demonstrated their role in such fundamental processes as targeting pathogens and moving lipid droplets in the liver for fatty acid regulation. His research gives in-depth knowledge on how to improve therapies for conditions such as obesity and diabetes. Professor Mallik has pioneered a new model system of the movement of single phagosomes on microtubules within living cells with the use of cutting-edge technologies. He discovered that cytoskeletal motor proteins of the dynein family use 'automatic gears' to enable them to function efficiently within large teams.

He also discovered that the geometrical structure of dynein is modified by their clustering into the cholesterol-rich lipid domain of phagosome membranes. This is important in understanding the destruction of pathogens contained within the phagosomes.

Professor Mallik did his postgraduation in Physics from Allahabad University and his doctorate from the Tata Institute of Fundamental Research (TIFR), Mumbai. He has studied/worked at TIFR, National Centre for Biological Sciences, Bengaluru and University of California, Irvine. He has been a recipient of the Shanti Swarup Bhatnagar Award for Biology in 2014.

The occasion was graced by the chief guest, Professor Manjul Bhargava, a Fields Medallist and R. Brandon Fradd Professor of Mathematics at Princeton University, USA, other eminent scientists and academicians, business leaders, young researchers and students. The trustees of the ISF, including Mr K. Dinesh, President of the Board of Trustees, Mr N.R. Narayana Murthy and Mr Nandan Nilekani were present.

P.M. NISCHAL, *Bengaluru, Karnataka*

A smart way to diagnose anaemia

Anaemia remains a global public health problem. In 2010, its global prevalence was 32.9% and resulted in 68.4 million years lived with disability. Measuring blood haemoglobin levels, the simple 'gold standard' test for the diagnosis of anaemia, is an invasive method which needs phlebotomy as well asspecialized equipment that is often inaccessible especially in rural India and other low-resource settings. Researchers from Georgia Tech and Emory University in Atlanta, USA, have devised a smartphone app for the non-invasive diagnosis of anaemia (Mannino RG, Myers DR, Tyburski EA, Caruso C, Boudreaux J, Leong T, *et al*. Smartphone app for non-invasive detection of anemia using only patient-sourced photos. *Nat Commun* 2018;**9:**4924). Anyone with a smartphone can download this app and immediately detect anaemia 'anywhere and anytime'. Utilizing photos taken through the app on a smartphone, the app detects anaemia by assessing the concentration of haemoglobin from the colour of fingernail beds. By analysing the colour and metadata of these photos, this app detects anaemia (defined as haemoglobin level <12.5 g/dl) with a greater accuracy than current non-invasive methods for screening anaemia. The app outperformed haematologists in physical examination-based measurements of haemoglobin levels. Considering the complete blood count-measured haemoglobin as the standard, this smartphone app was found to have an accuracy of ±2.4 g/dl and a sensitivity of 97% (95% CI 89%–100%). The authors reported that personalized calibration techniques can be used to further improve the accuracy of the app. In the point-of-care settings, the accuracy of this app was found to be on par with the invasive but clinically used *Hemocue* and outperforms other under-development screening tools (e.g. HemaApp) and conjunctival analysis via photographs.

Dr Y.S. Raju (Professor and Head, Department of General Medicine, Nizam's Institute of Medical Sciences, Hyderabad, Telangana) told this correspondent: 'Given the ubiquitous availability of smartphones globally, this app has the potential to function as an effective screening tool for anaemia in the field setting and can facilitate self-testing as well. However, issues such as user error, inter- and intra-smartphone variability in haemoglobin measurement, among others merit further study before this technology can become a standard of care.'

ALLADI MOHAN, *Tirupati, Andhra Pradesh*