Role of materiovigilance in COVID era: An update

Materiovigilance is the close monitoring of any undesirable performance or characteristic fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting and reacting to them, with field safety corrective actions or device recalls, during the post-marketing phase of a medical device.[1,2] It entails medical devices and in-vitro diagnostics whereas, pharmacovigilance includes close monitoring and post-marketing surveillance of medicines. Medical device refers to any instrument, apparatus, machine, appliance, implant, reagent, calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease.[3] After several horrific cases associated with malfunctioning of medical devices such as infants getting burned to death due to short circuits in incubators, or hip implant causing metal leaching blood poisoning,[4-6] the Ministry of Health and Family Welfare (MoHFW), Government of India have approved the Materiovigilance Programme of India (MvPI) in February 2015.[1,2] Its mission is to safeguard the health of Indian population by ensuring that the benefits of the use of medical devices outweigh the associated risk, similar to what is expected with the use of medicines.

In the ongoing COVID-19 pandemic, various medical devices are being used for prevention or treatment of the disease. These include masks, respirators, ventilators, personal protective equipment (PPE) kits, in-vitro diagnostic (IVD) kits, sanitizers and many more. As per various media reports, counterfeit and substandard quality medical devices are freely available in the Indian market which can lead to serious risk to the health of both the patients and the healthcare providers. Hence, strict vigilance of medical devices is required to eliminate the use of such medical devices which do not meet the minimum quality requirements. Batches of such medical devices can also be recalled from market by the manufacturers or authorised agents, if needed. Recall means any action taken by its manufacturer or supplier to remove or withdraw the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the device is hazardous to health.[4]

Evidence for infrared thermometer from meta-analysis shows that the pooled sensitivity, specificity and AUC (Area Under the Curve) of infrared tympanic thermometers in children over 1 year were 0.80 (95% CI 0.78-0.81), 0.94 (95% CI 0.92-0.95) and 0.95, respectively. Further, the diagnostic accuracy of infrared tympanic thermometers in children with hyperthermia has been reported to be low.[5] There has been a lot of conflict regarding the usage of non-contact infrared thermometer, but a few studies also recommend it for a mass-level use in situation of pandemics, for both adults and children.[6,7]

N-95 respirators and surgical masks are examples of PPE that are used to protect the wearer from airborne particles and liquid contaminating the face. The Centre for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) regulate N-95 respirators.[8,9] CDC does not recommend that the general public should wear N-95 respirators to protect themselves from respiratory diseases, including COVID-19. These are critical supplies that must continue to be reserved for health care workers and other medical first responders.[10] It also recommends that people should use simple cloth face coverings when in a public setting to slow the spread of the virus. A surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and the potential contaminants in the immediate environment. An N-95 respirator is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The 'N' means nil for oil-based medium particles while '95' signifies that it can filter 95% of the airborne particles.

Under the MvPI, Indian Pharmacopoeia Commission, Ghaziabad (IPC, Ghaziabad) functions as the National Coordination Centre (NCC) and Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST) functions as the National Collaborating Centre. Medical Devices Adverse Events Monitoring Centres (MDMCs) have been established for monitoring, recording and reporting of medical device adverse events (MDAEs). Under the MvPI, clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses and technicians can report medical device related adverse events. As a stakeholder, it is our responsibility to report such adverse events and safeguard the health of the public. In order to foster the habit of reporting, MvPI encourages reporting of all types of adverse events related to medical devices – irrespective of whether they are known or unknown, serious and non-serious, frequent or rare. The causality assessment will be performed by the NCC team comprising biomedical engineers, technical partners and healthcare professionals.

The IPC has developed a PPE form to promote safety of healthcare professionals and general public. Using this form, we can report quality related issues about gloves, coverall, googles,

N-95 respirators, shoe covers, face shield, body bags, triple layer medical mask, sanitizers, etc., This form is freely available on the official website of the IPC.[11] The duly signed form can be sent to the nearest MDMC or can be directly sent to the NCC. It can also be scanned and mailed to mvpi.ipcindia@gmail.com. The reporter can also call the toll-free helpline number created by NCC-MvPI (1800-180-3024) and report the adverse event.

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Conflicts of interest

There are no conflicts of interest.

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