Medical technology and patient safety

Dr. Niranjan D. Khambete, Manager, Clinical Engineering, DMH&RC

Important role of technology in modern medicine

In the present era of modern medicine, it is equivocally accepted that technology plays a crucial role in achieving effective delivery of healthcare services to patients, thus bringing tremendous benefits to them in many ways. Furthermore, advancements in technology continue to provide novel and improved solutions for satisfying the emerging unmet clinical needs.

Technology is used in many different forms in medicine. 'Medical Technology' is at its core because it plays a direct role in diagnosis, prevention and treatment of diseases and also in rehabilitation. Advanced computing technology has transformed modern medical equipment and extensive use of Information and Communication Technology has revolutionised healthcare systems by providing tools to manage large volumes of clinical data. Interestingly, technology has also been effectively used to provide solutions for enhancing patient safety.

Technology and the principle of '*First do no harm'*

While technology continues to bring significant benefits to patients and other stakeholders, it is important to keep in mind that the longstanding medical principle *'First do no harm'* [1], needs to also form the basis of its development as well as day to day clinical use. Patient safety should not be compromised due to any unforeseen effects of this technology. However, contrary to this expectation, evidence from the literature suggests that patient safety can be compromised if the safety aspects of technology are not identified and addressed systematically.

The magnitude of this problem can be judged just from one instance in which 56000 patient safety incident reports associated with just one medical device, the infusion pump, were received by the Food and Drug Administration of the USA between 2005 and 2009 [2]. In India too, recent studies and newspaper reports have voiced safety concerns with medical technology. They report that medical devices such as electrosurgical units [3], neonatal incubators [4, 5], X-ray units [6] and MRI imaging systems [7] have been implicated in incidents causing serious harm and even death to patients. Furthermore, absence of regular checks on life saving equipment used in medical college hospitals has also been a cause of concern [8].

Addressing patient safety issues throughout the medical technology lifecycle

Before medical technology is formally introduced into routine clinical use, it goes through multiple sequential stages of its lifecycle from conceptualisation to disposal. The initial stages of this lifecycle include research and development, laboratory testing, pre-clinical evaluation and several phases of clinical evaluation. At each of these stages a careful consideration needs to be given not only to the functional performance but also to the safety requirements. A battery of international standards developed by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC) provide detailed information for satisfying these requirements. There exist many device specific standards as well as generic performance and safety standards, which cover majority of the commonly used medical devices. In addition, the generic standards which provide guidance on applying quality management systems and risk management to medical technology further strengthen the focus on patient safety issues [9].

Medical Device Regulation – an effective mechanism to ensure patient safety

Medical Device Regulatory Authority, which is mandatory in most industrialised countries, plays a vital role in ensuring safety of medical technology. It acts as a 'gate keeper' in ensuring that, through rigorous evaluation process, only safe and effective medical devices are introduced into routine clinical use. The classification of medical devices into four classes based on the level of potential risk presented by them in use, helps in rationalising the testing and evaluation protocols.

The European Medical Device Directive classifies medical devices into four classes, namely Class I devices having low risk (e.g. urine collection bag and walking aid); Class IIa devices having low to medium risk (e.g. hearing aids and electrocardiographs); Class IIb devices having medium to high risk (e.g. syringe pumps and ventilators) and Class III devices having high risk (e.g. balloon catheters and prosthetic heart valves) [10]. The performance and safety requirements and intensity of testing become progressively more stringent as the devices ascend the Class. The 'Notified bodies', are the third party entities recognised by the regulatory authority to carry out the actual conformity testing on prototypes based on the Class of the device.

Thus, finally the regulatory authority reviews the 'technical file' which consists of data collected at various initial stages of the medical technology lifecycle as well as during the testing carried out by the notified body, and declares whether the device under consideration is safe and effective for routine clinical use. Furthermore, in order to ensure consistency in quality of manufactured medical devices, the regulatory authority has the mandate to enforce quality management and risk management standards on manufacturers.

Safety of medical technology in routine clinical use

Patient safety issues associated with medical technology need continued attention, even after it is introduced into routine clinical use. For example, training of clinical staff and clinical engineering professionals is essential before the first use of any medical equipment. For longer term safety, effective medical technology management systems have to be in place for planning and execution of periodic calibration, safety testing and preventive maintenance, which ensures that only well performing and safe medical equipment is available for use at all times. Accreditation of these management systems can further reinforce medical technology safety.

The patient safety incident reporting and analysis systems, if implemented in conjunction with transparent and non-punitive work culture, can effectively capture and mitigate patient safety issues of medical technologies. In the same way, post market surveillance and vigilance systems can capture long term safety aspects of medical implants, which is a combined responsibility of healthcare providers and manufacturers.

In summary, the use of technology in modern medicine is ubiquitous and has brought immense benefits, but it is important to acknowledge that there exist inherent risks in its use. Therefore, systematic efforts at multiple levels in the development as well as use of this technology are warranted to ensure that patient safety is never compromised. In the final article of this series on patient safety, role of Clinical Engineering Professionals in enhancing medical technology safety and patient safety will be discussed.

References

[1] Kantarjian, Hagop and Steensma, David (2014) Relevance of the Hippocratic Oath in the 21st Century . *The ASCO Post*, 5 (16). Downloaded from the website: http://www.ascopost.com/issues/october-15,-2014/relevance-of-the-hippocratic-oath-in-the-21st-century.aspx on the 31st December 2014

[2] Food and Drug Administration, USA (2015), Infusion Pumps, Downloaded from the website: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htom, on the 28th April 2015.

[3] Khambete N, Kelkar-Khambete A, Desurkar V, Murray A. (2013) Safety testing of medical equipment in hospitals and its implications for patient care in India. IFMBE Proceeding;39.

[4] Khambete N, Sable S. (2013) Neonatal incubators: are new born babies really safe? IFMBE Proceedings;39.

[5] Staff Reporter (2009). Five infants burnt alive as incubator catches fire. Indian Express 31 January.

[6] Parthasarathy KS. (2008) Dismal state of medical X-ray safety. The Hindu 5 June.

[7] Mishra L.(2014.) Two stuck to MRI machine for 4 hrs. Mumbai Mirror 11 November

[8] Maya C. (2013) Life-saving machines in medical colleges get no check-up. The Hindu 11 Nov

[9] Newton RC. e*t al* (2010)*,* Making existing technology safer in healthcare , Qual Saf Health Care 2010;19(Suppl 2):i15-i24

[10] European Commission - DG Health and Consumer Directorate B, (2010) Medical Devices Guidance Document: Classification of medical devices, MEDDEV 2. 4/1 Rev.