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Tools & Techniques for Assessing the Performance of Medical Devices

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Abstract

Medical devices and health technology are imperative for human health. Medical devices are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. According to WHO inappropriate deployment and use of medical devices is increasing. US FDA, recall of medical devices is very high Realizing the important role of health technology and medical devices there is a great need to establish the global domains and methods in the selection and management of health technologies, specifically for medical devices. The global objective of assessment is to ensure improved access, quality and use of medical devices. These objectives will create a frame work that will have a positive impact on burden of disease and ensure effective use of resources. The aim of this review was to meet these objectives by assessing the medical devices using technical, clinical, financial and operational tools.

Abbreviations

MD: Medical Devices; FDA: Food & Drug Administration; HTR: Health Technology Regulation; HTM: Health Technology Management; MTAC: Medical Technology Advisory Committee

Introduction

Medical devices play a growing role in the diagnosis and management of disease [1]. Extensive use of medical devices for the treatment and prevention of acquired, inherited, traumatic, or degenerative lesions in the body generated a tremendous need for newer technologies and tools. Medical devices have been employed empirically for more than 2000 years but their use has increased over the last 40 years [2]. In a response to an ever increasing demand for improved quality of life, emerging technologies, and scientific tools have opened up new areas for MD application. Medical devices have made a significant contribution in helping patients to enjoy longer lives of good quality. However, numerous weaknesses in premarket evaluation and post-market surveillance that have sometimes lead to unexpected and serious safety problems [3]. FDA over a 5 year period, recalled 78% of high risks medical devices. High recall of MD in recent years pose substantial risks to patients. Number of safety recalls has been reported by FDA on MD like breast implants [4] specific types of artificial hips [5] devices for lung surgery [6] and implantable cardioverter-defibrillator leads [7]. According to FDA data, agency typically recalls 13-75 devices each day, majority of those recalls are either of class II or class III recalls [8] (Figure 1). Recently in August & July 2015 most serious MD like Micro Port orthopedic & Omnni Pod Insulin Management System was withdrawn from the market. Micro Port orthopedic has a variety of hip joint replacement systems that allow the surgeon to fit the implant specifically to the patient. Recently it has received the reports of an unexpected rate of fracture after surgery related to specific modular neck. The patient experienced pain, instability, difficulty in walking and performing common task. Acute fracture is a serious health consequence and could lead to neurovascular damage, hemorrhage and even death [9]. The OmnniPod Insulin Management System is an insulin pump used to deliver insulin to people with diabetes. 'Insulet' has identified 2 issues, one is that the tube either fails to fully insert into the skin or completely retracts after insertion. This failure occurs without an alarm and the Pod will continue to pump insulin. Other one is that the Pod will provide an audible alarm signal and display a failure. Once the alarm occurs, the Pod will not pump insulin that it resulted in inaccurate dosage of insulin which can lead to high blood sugar levels. If left untreated, hyperglycemia can cause life threatening conditions or even death [10]. These episodes have led medical experts to call for greater performance evaluation of MD. Therefore it is of paramount importance to evaluate pre and post marketing performance of medical devices to ensure that its benefits outweigh risks in actual use in more number of patients over time. The technical performance must be

distinguished from the clinical benefit; the clinical benefit that can be dependent not only on the MD itself but also on the performance of the medical team and the technical expertise [11]. Healthcare delivery systems around the world are going through major transformations. Medical technology plays a significant role in healthcare transformation. To ensure that the medical technology is safe and effective, there is need to understand the potential of technology and importance of associated management tools. This newsletter addresses the efficient and effective methodology for the assessment and deployment of MD. The MD need to assess using technical, clinical, financial and operational aspects. These assessment tools would evaluate the performance of MD in terms of safety, efficacy, effectiveness and organizational dimensions, psychological, social, ethical, and economic aspects.

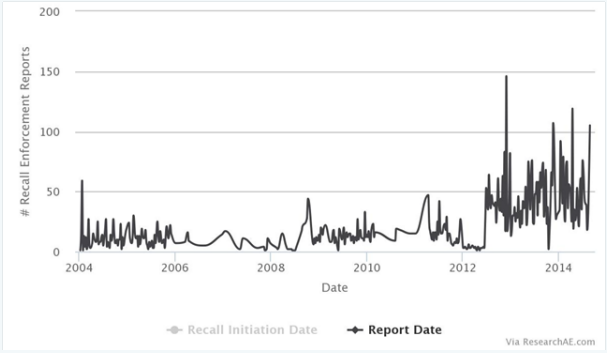

Figure 1: Recall trends

In November 2012 there was massive recall of 146 devices and in April 2014 recall of 119 devices. Overall number of device recall events has dramatically surged since June 2012. In 2015 most serious MD recalls were noted and these products could cause serious health problems or death.

Domains of MD Assessment [12] (Figure 2,3)

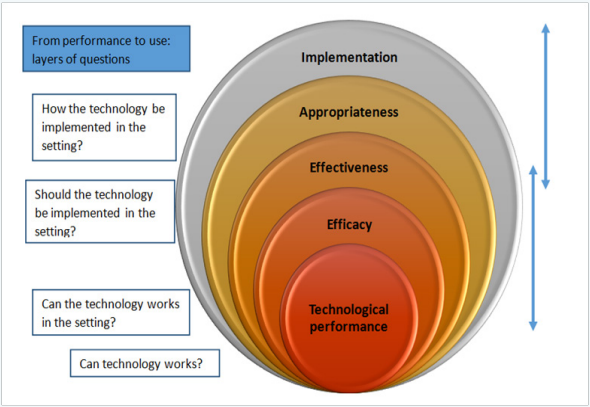

Figure 2: Health technology regulation (HTR), assessment and management (HTM) are complementary functions to ensure the appropriate introduction and use of medical devices.

Figure 3: Domains of health technology regulation, assessment and management for medical devices.

Methods of MD Assessment (Figure 4)

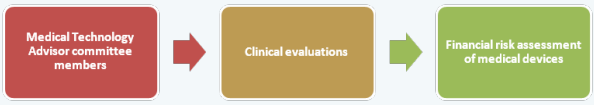

Figure 4: The paradigm of Technology assessment of MD emerged as a response to decision-makers questions about uncontrolled use of costly MD. The systematic evaluation may avoid intended or unintended consequences.

MTAC Members

As medical technology continues to evolve, so does its impact on patient outcomes, hospital operations and financial resources. The ability to manage this evolution and its subsequent implications has become major challenge in all healthcare organizations. In the technology assessment phase Medical Technology Advisory Committee (MTAC) members needs to contribute to the performance evaluation process. A Medical Technology Advisory Committee member assess the major MD in the hospitals to determine how well the existing technology base supports its function. MTAC members also assess the need of new and emerging technologies. In this assessment, following issues must be considered [13].

1. Need of new and emerging technologies as well as evaluate the impact of these technologies on the clinical services.
2. Value of the technology
3. Vendor evaluation
4. Technical validity
5. Ability to assimilate the technology
6. Ability to integrate with existing technological platforms
7. Medical staff satisfaction
8. Impact on staffing and delivery of care
9. Impact on facilities
10. Impact on standards of care and quality
11. Economic considerations

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In-House Clinical Evaluations

In house clinical evaluations should never be confused with a clinical trial. The In-house clinical evaluation process uses nursing or clinical staff members as a part of their normal clinical practice or nursing protocol. The clinical staff will evaluate MD based on the clinical criteria which includes monitor visibility, range, and clarity of signal, ability to program the device and human-factors elements. Clinical evaluation extends laboratory and engineering aspects interjecting the clinical environment, including the patient, the user and facility. Clinical evaluation includes examining the performance, ease of use, human factors and safety aspects of the MD [14].

Following issues must be considered for In-house clinical evaluation

1. Assess MD compliance with essential principles or requirements [7]
2. Assess the clinical evidence required to support medical device conformity based on actual usage of the device.
3. MD entering the facility should be subjected to full incoming inspection testing
4. Gain the clinical experience of others associated with use of MD
5. Collection of the information about the specific technology being requested
6. Identification of the other clinical procedure for which the technology can be used
7. Collection of the information about the alternative technologies that could be used for same clinical procedures.
8. Comparison of the requested and alternative technologies
9. Examination of the clinical efficacy of the requested or alternate technologies
10. Determinations of the risks and hazards associated with use of MD
11. Comparison of the requested and alternative technologies to the existing technologies within the organization.
12. Public health benefit: In particular its impact on the health of the population, in terms of mortality, morbidity and quality of life, its ability to fulfill a therapeutic or diagnostic need or to compensate for a disability [7].
13. Performance of a conceptual needs analysis based on all of the above information

In-house technical evaluation should involve maintenance and interface related criteria such as mean time between failures, features of hardware and software's, cost of parts, cost of the system, and cost of ancillary parts, installation requirements, and availability of clinical and technical training. In-house assessment process can be accomplished using a weighted matrix or ranking system for decision making. A weighted matrix is valuable in selecting best equipment to purchase for specific area of priority.

Financial Risk Assessment of MD

The financial risk evaluation for MD means not only the risk of physical injury or facility damage but also financial risks that the technology may pose as well, e.g., underutilization, unacceptable dedication of financial resources, loss of clinical specialists, MD failures, negative publicity, or potential losses. The aspect of technology evaluation can be a "make or break" item, more often decisions are based on comparison of many aspects, with financial risk being significant.

Challenges for Using Technology Assessment in Developing and Emerging Countries

Certainly implementing an advance medical technology in the developing country or in wealthier nations is very difficult and disappointing. There can be substantial reasons or differences in epidemiological environments, financial resources, cultural acceptance of healthcare interventions, technology maintenance capacity, civil and healthcare infrastructure, skilled human resources, training and education, regulatory environment, and health professional standards. These challenges are for the global community to work with multidisciplinary approach and to facilitate use of advance medical devices for the benefit of the patient in developing and emerging countries.

Discussion &Conclusion

MD assessment is an important part of healthcare operations. Throughout the process it requires the cooperation of many professionals, including clinical engineers. It offers the opportunity for the development of alliances and sharing of information for the benefit of the patients. If performed properly, it can provide a means for rational decision making that is acceptable in the clinical community. It can help to make the use of best human and financial resources in a healthcare industry. Finally, it is essential to acknowledge that cost is a primary concern in health-care systems worldwide and a key driver of technology assessment. Therefore, cost utility analyses are an integral part of any MD assessment. Ultimately, the quality of these and other assessment tools will guide decisions that significantly affect the delivery of health care.

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