A Review on : Materiovigilance in Practice of Pharmaceutical and Other Healthcare System

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OBJECTIVE

Materiovigilance (Mv) has the same purpose and approach in ensuring patient safety as harmacovigilance but deals with medical devices associated with adverse events (MDAEs) and their monitoring. Mv has been instrumental in recalling many defective or all functioning devices based on their safety data. All MDAEs, such as critical or non-critical, known, or unknown, those with inadequate or incomplete specifications, and frequent or rare events should be reported and evaluated.

Mv helps to improve medical devices' design and efficiency profile and avoid device-related complications and associated failures. It alerts consumers and health professionals regarding counterfeit or substandard devices. Common events reported through Mv are device breakage and malfunction, entry- and exit-site infections, organ perforations or injuries, need for surgery and even death, and life cycle assessment of devices. Health authorities globally have developed reporting frameworks with timeframes for MDAEs, such as MedWatch in the USA, MedSafe in New Zealand, and others. Health professionals and consumers need to be made aware of the significance of Mv in ensuring the safe use of medical devices and getting familiar with the reporting procedures and action plans in case of a device-induced adverse event.

KEYWORDS

Device recall, Materiovigilance, Medical devices, Medical devices associated adverse events (MDAEs), Pharmacovigilance, Regulation, Reporting guidelines

1. INTRODUCTION

The term "vigilance" means close monitoring of the possible adverse effects [1-4]. Materiovigilance is the study of adverse events associated with the use of medical devices. It deals with the close monitoring of medical devices after post-marketing phase [1, 5]. The term "medical device" has been defined by the World Health Organization (WHO) as any instrument, apparatus, reagent for in vitro use, implant, device for tissue cutting or wound covering, highly sophisticated computerized medical equipment, software or other related or similar materials which are intended to be used for diagnosis, prevention, monitoring, treatment of disease [1, 4-8]. Although, the medical devices provide immense benefits to the patients, but the use of medical devices may also lead to some significant potential risks, sometimes life threatening [1, 7]. The risks that are associated with the use of medical devices include harmful effects, in

particular, on the patients/users/healthcare professionals, interactions with other substances, certain contraindications and malfunctions. The risks can also include falsifications, technical defects and reduced efficacy [2, 6, 9-13]. This makes it essential to have a regulatory program to monitor these associated adverse effects. Materiovigilance deals with the identification, collection, reporting, estimating the undesirable occurrence and the possible management of adverse events associated with the use of medical devices, thus promoting patient health by preventing its recurrences [1, 5, 7]. The Materiovigilance program of India was launched on 6 July 2015 at the Indian Pharmaceutical Commission, Ghaziabad by DCGI [1, 2, 5] in order to track the medical devices and the associated adverse effects to ensure the safety, provide awareness, generate data, and promoting the patient safety [5, 7].

1.1 Materiovigilance program of India (MvPI):

In India, medical devices are classified as drugs and are regulated by drugs and cosmetic act and rules 1945 [6, 7, 16, 18]. The MvPI is required to regulate the quality, efficacy, safety and availability of medical devices. The medical device rules, 2017 was brought to regulate the manufacture, import, sales, distribution of medical devices and came into force from 1 January 2018 [17]. The Central Licensing Approving Authority in October 2005, declared 10 devices to be considered as drugs. Medical devices which are classified as drugs include cardiac stents, drugs eluting stents, contraceptive implants, catheters, bone cement, i.e. cannula, intraocular lenses etc. [6, 14]. The MvPI aims at monitoring adverse events associated with the medical devices (medical device associated adverse events). The MvPI includes all private and public health care delivery system as well as the e-reporting system [2]. The MvPI was approved by Ministry of Health and Family Welfare on 10/2/15 and it was launched on 06/7/15 by DCGI at IPC, Ghaziabad, India [1, 5, 15,17].

1.2 Medical device regulations 2002:

Medical Device Regulations 2002 has been made on May 20, 2002, and came into force on June 13, 2002. Under section 2 of the European Communities Act 1972, the Secretary of State is a Minister is designated for the purpose of section 2, to take measures relating to medical devices, with the powers conferred by section 56 and of Finance Act 1973, i.e. in exercise with the consent of the Treasury, in exercise of the power under section 11 and 27 and in exercise of all the power after consultation in accordance with section 11 enabling him in that behalf, of Consumer Protection Act 1987, with the organization that appears to be representative of interest which are markedly affected by these Regulations and other persons which he considers appropriate and with the Health and Safety Commission [3].

Recall of devices While marketing a device, the manufacturer, distributor, or consumer might report complaints as some quality defects. If a complaint about a defect is not justified, then it is considered a failure of the quality system and immediate corrective action is undertaken by a product recall. The guidelines of MHRA [6,19] and GHTF [6, 16] have termed recall a Field

Safety Corrective Action (FSCA) to reduce the risk of harm to patients, operators, or others or to minimize the reoccurrence of the event. The FSCA would include the following actions:

Return of a medical device to the manufacturer or its representative (which is termed recall). Device modification.

Device exchange.

Device destruction.

Advice is given by the manufacturer regarding the use of the device.

The FSCA could reckon on different gait such as the return of a medical device to the supplier; device modification, exchange or destruction; retrofits by the purchaser of manufacturer's modification or design change [6]; and any advice being given by the manufacturer on the use of the device. However, the manufacturer must distribute a Field Safety Notice (FSN) by appropriate means such as by confirmation of receipt. The FSN itself should include the following items:

- A clear title like "Urgent Safety Notice" on the notice itself, on the envelope, if sent by mail, and as the subject line if sent by email or fax.
- The intended audience: a clear statement about the intended recipient of the notice.
- A concise description of the subject device (model, batch, or serial number).
- The reasons for the FSCA are explained by the certain factual statement.

The notice must also include a request to inform customers or patients who received the product. The recalls have been classified on the basis of associated relative health hazard by both FDA and TGA as follows:

Class I: where severe adverse health consequences or death are likely.

Class II: where temporary or medically reversible health consequences are likely.

Class III: where use or exposure to the offending product will not likely cause adverse health consequences.

Class I or class II recalls are considered to be urgent safety-related recalls, whereas class III recalls are considered to be routine non-safety-related recalls. In addition, the TGA has classified recalls on the basis of the two-phase as premarketing and post marketing phases [6, 20].

1.3 Premarketing phase

- The manufacturer submits a device for assessment along with plans to monitor the performance of devices in use along with the response to any difficulty that may occur to the notified body.
- The notified body conducts a conformity assessment for approval. In case of acceptance, 'CE' mark to the device will be certified to the manufacturer and the notified body also approves the system for monitoring the device's performance and safety.

- Medical Devices with 'CE' marking can be recognized mutually across all the European Union (EU) member states [2, 21].

1.4 Post marketing phase

- All the adverse events are monitored by the manufacturer during the use of their device and necessary action is taken which is also known as FSCA for the reduction in the risk of death or serious fall in the state of health associated with the use of a medical device that is placed in the market.
- The adverse incident report related to the device is monitored by the competent authorities in each state (EU member) in their own country, along with the manufacturer's investigation and responses.
- Materiovigilance is designed to generate information for the identification of the problems related to the use of medical devices for the facilitation of the development of safety devices [2, 4, 21].

1.5 Applications of materiovigilance :

- Diagnosis, monitoring, prevention, treatment, or mitigation of disease or compensation for an injury.
- Improvement in design and efficiency of medical devices.
- Reporting and investigation of the medical device-associated
- adverse events.
- Implementation of corrective actions to prevent adverse events in future [1, 6, 27].
- Investigation, replacement, modification, or support of the anatomy or a physiological process.
- Supporting or sustaining life.
- Control of conception.
- Disinfection of medical devices.
- Providing information for medical purposes by means of in vitro

1.6 Medical device tracking

Medical device tracking has been included by the FDA as one of the post-marketing activities in order to track the device from the time of its manufacture up to the end-user [6]. Medical device tracking helps in locating the device in case of any defect or problems with the device [6, 24, 25, 22]. According to the FDA Act, there are certain devices which require tracking such as implantable devices, lifesustaining or life-supporting devices, the failure of such devices will result in serious consequences [5, 6, 24]. The regulations implemented for the tracking of medical devices became effective on29 august 1993 and can be found in 21 CFR part 8216 [23]. The manufacturer is required to submit the information regarding the medical device whether the device has not or has been distributed to a patient within a period of 3-10 d [6]. The

manufacturer needs to establish a written standard operating procedure for tracking the medical device which includes methods and other information regarding the tracking of the medical devices [24, 23]. The tracking is generally performed for any type of class II and class III devices. TGA has developed an Implantable Medical Device Tracking Subcommittee (IMDTS) for tracking of patients with implantable medical devices. However, in Europe, the Adverse Incident Tracking System (AITS) has to be followed. The adverse events can be categorized into one of the following investigational categories according to the revised MHRA directives [6].

In India, a lot number or a batch number is assigned to each device in order to make the tracking process easier. While assessing the link between the device and the adverse event, the manufacturer must take into account the following details:

- Opinions from health care professionals
- Previous similar events
- Complaints trends
- Other information held by the manufacturer

Clinical Investigation or case study about materiovigilance:

Clinical Investigation or case study about materiovigilance Mahajan et al., reported the impact of manufacturer advisories and FDA recalls of implantable cardioverter-defibrillator generators in paediatric and Congenital Heart Disease (CHD) patients from the year 2000-2005, it was found that about 25% of total patients had recalled devices and a significant proportion of patients underwent explantation. All these complications, though infrequent have important medical as well as psychological impacts and need to be monitored [24]. Beydon et al., studied adverse event reports associated with the medical devices used in anesthesia and intensive care in France. There was about 1004 adverse event reports in the year 1998 and about 11% cases were classified as serious and 2% deaths were also reported. There were several causes of failure of medical devices, the leading ones were user errors, quality control problems during the production of the devices and the design fault.

32% of all reports in France was accounted for anesthesia in 1998. While 98% of the incidents were not fatal, but they required further examination as the problems with them were same as in the fatal incidents [25]. Laskey et al., performed an analysis of implantable cardiac device reliability from 2003-2007 in the United States. Data reports of devices such as Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) implants, explants, and returned devices were analyzed. A statistically significant decrease in implantable cardiac device explanation was observed from year 2003-2007. However, the explanation rates of CRT-D devices remained significantly higher than ICD devices [25]. Golder et al., studied the failure or success of search strategies to identify adverse effects of medical devices and it was found that 51 were included on MEDLINE and 55 were included in EMBASE. Seven of EMBASE were found to be duplicates. Hence, creating a search filter for adverse effects of medical devices is reasonable and should be a research priority [26].

2. CONCLUSION

In a few recent years, the use of medical devices is found to be very frequent by medical practitioners all over the world. Despite that, there are no substantial rules and regulations to protect the patients from aversive events related to the use of medical devices.

Materiovigilance program is a good initiative by the different countries to ensure the safety of medical devices among the device users globally. This is requisite that emphatic implementation of this program will indemnity the safety of device users or patients. Thisprogram will be also significantly reducing the risk related to the use of medical devices by preventing the reduplication of aversive effects.

3. AUTHORS CONTRIBUTIONS

This review article was initiated and designed by Dr. Anand Chaurasia. All the work has been contributed by him.

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