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Review Paper

Review On Material Vigilance

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ABSTRACT

Material vigilance is an important component of global healthcare regulatory framework. It is dedicated to the systemic monitoring and adverse events reporting of medical devices. This article gives information about the material vigilance which includes the classification of medical devices, need of materiovigilance, some programme related to materiovigilance like (Mvpi) with regulatory systems in other countries and many more. It highlights the need of surveillance to ensure patient safety throughout a medical device's lifecycle. Central of this article are two case studies the first case is of Johnson & Johnson's metal on metal hip implants, this shows the systemic failures in early warning detection. The second case study is on Bayer's Essure permanent birth control device which also leads to product recall in some countries, this a indicates the need of materiovigilance or post marketing surveillance of medical devices. Together, these cases indicates the needs of materiovigilance in identifying longterm risks that clinical trails may fail to capture.

INTRODUCTION

Materiovigilance is the close monitoring of any undesirable performance or characteristics fluctuations of a medical device which can cause harm to the patient or consumer, the post marketing testing of medical devices is called Materiovigilance. According to WHO, a medical device can be defined as any instrument, apparatus, machine, appliance, implant in-vitro reagent or calibrator, software, material or other similar or related article, manufactured by the manufacturer to be used, alone or in combination, for human beings for the purpose diagnosis, prevention, treatment, or alleviation of disease[1].Medical devices are widely used to diagnose, prevent, and treat different diseases [2] and range from simple meter dose inhalers to complicated operation theatre and radiology devices. The global demand for medical devices

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has risen exponentially and reached 380 billion USD in 2016 from 260 billion USD in 2006, with the burgeoning incidence of stroke, obesity, diabetes, cancer, and many other chronic diseases[3,4].

Despite the fact, medical devices provide benefit to the patients, its use is not completely devoid of risk. It can cause morbidity and mortality in the patients or users of medical device[5].Many medical devices like catheters, infusion pumps were recalled due to malfunction since these may cause serious injuries or death [6], [7] .Therefore, it is very important to analyse the benefit-risk ratio of medical devices and to generate evidence based information on safety of medical devices during the premarketing development phase of the medical devices [8]A similar concept and approach of Pv have been incorporated in medical devices, termed materiovigilance (Mv).WHO defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. The term now also encompasses the problems related to the use of herbals, traditional and complementary medicines (especially relevant to population in our country), blood products, biological, medical devices and vaccines[9].Materiovigilance have similar function like pharmacovigilance but the only difference is that the materiovigilance deals with the testing of medical devices and the pharmacovigilance deals with the testing of medicines. Materiovigilance is the close monitoring of any undesirable and unwanted performance or characteristics 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 recall during post – marketing phase of a Medical Device.[10]The Ministry of Health and family Welfare (MoHFW) has approved commencement of "Materiovigilance Programme of India (MvPI)" on 2015 in an effort to ensure safety of medical devices and also to generate awareness among health care professionals towards the importance of reporting of medical device-associated adverse events (MDAE) and thereby establishing reliable evidence-based safety data of medical devices[11]. The aim of this article Is to highlight the need of Materiovigilance to prevent the reoccurring harm caused by medical devices to the patient or consumer and how to report adverse reactions to the regulatory authorities like CDSCO.

❖ GLOBAL MATERIOVIGILANCE INITIATIVE :

The International Medical Device Regulators Forum (IMDRF), includes10 countries, such as the USA, Japan, EU, China, South Korea, and India, was set up in 2011 to introduce and implement the concept of the Mv program to monitor medical devices associated adverse events (MDAEs) and to harmonize international medical device regulation through Mv [12]. The materiovigilance program of India (MvPI), launched on July 6, 2015, helps to systematically collect safety data on device used by Indian population, to monitor MDAEs, to raise awareness among health professionals on their reporting, to monitor benefits and risks, to generate evidencebased suggestions on safety, and to communicate findings to the stakeholders and regulatory authorities [13 14, 15, 16].

INDIA:

The regulatory system for medical devices in India is still developing. The Central Drugs Standard Control Organisation (CDSCO) is the regulatory body supervise the regulation of medical devices in India. The regulation of medical devices in India is governed by the Ministry of Health and Family Welfare, which classifies medical devices into

four categories based on their risk levels.i.efrom class A to classD. The lowest risk is posed by Class A devices, whereas the highest risk is posed by Class D devices.

CLASSIFICATION OF MEDICAL DEVICES:

The classification is based on various parameters such as of contact time with the body, how intrusive it is, and the risk of injury ,the classification of medical devices is divided into four class i.e,fromclass class A to classD. Surgical equipment, wheelchairs, and bandages are examples of Class A devices. Needles, syringes, and catheters are examples of Class B devices. Orthopaedics implants, implanted pacemakers, and cardiac stents are examples of Class C devices. Drug-eluting stents, implanted defibrillators, and prosthetic heart valves are examples of class D devices. The classification scheme aids in making certain that the regulatory safeguards are in place to protect patient safety and advance public health [17].

INDIAN SCENARIO ON MATERIAL VIGILANCE:

In India, the regulation of medical devices also includes the implementation of materi-o-vigilance to control unfavourable consequences brought on by these devices. Materi-o-vigilance includes observing and tracking incidents brought on by medical technology[18].The Materi-o-vigilance Programme of India (Mv-PI) was established in 2015 to generate safety data, develop awareness among stakeholders, and recommend best practices for patient safety. It is still a debatable topic if India's regulatory system is successful in terms of its capacity to keep up with changes in the global medical device regulation environment [19].

The CDSCO introduced its 'Sugam Portal' online licensing portal for medical device registration in November 2015 [20]. In India, medical device laws have improved over the past 20 years due to the growth in the quantity, variety, and complexity of medical devices So, it is very important to track and test the medical devices on regular time intervals to maintain there safety towards the patients .It is believed that national medical device regulation harmonization is required to lower regulatory barriers and offer timely access to safe and effective medical equipment [21,22].

✓ CASE STUDY ON FAILURE OF MEDICAL DEVICE IN INDIA :

Deputy International Limited (DePuy), a United Kingdom subsidiary of Johnson and Johnson, developed a hip replacement device which is an metal-on-metal design having cobalt, chromium and molybdenum as the major constituents. Normally in hip replacement surgery, the natural ball and socket of the hip are replaced with an artificial ball and socket. Traditional hip replacements use metal and polyethylene parts that eventually wear down, whereas the ASR system utilizes a metal-on-metal design. This alternative approach aims to increase durability and provide patients with a superior range of motion. Hip replacement surgeries are recommended in cases where the hip joints have degenerated over time or were deformed since birth, or were damaged in an accident. Once reserved for those over 50, this procedure is now frequently performed on adolescents dealing with paediatric hip conditions like juvenile arthritis.

DePuy manufactured and sold the ASR XL Acetabular System and ASR Hip Resurfacing System in 2003. After FDA clearance was achieved via the 510(k)approval process, ASR implants were launched in the United States in 2008. The premarket notification, popularly known as the 510(k)-approval process, preapproves products that are deemed

"substantially equivalent" to those already legally approved for sale, requiring no clinical trials and typically taking an average of 3-6 months to complete[23].In Europe, ASR implants have become available under the "substantial equivalence" clause, allowing expedited market approval[24].

By late 2006, J&J had secured official permission to bring ASR implants into India through a drug authority channel. Yet records point further back – to 2005 or early 2006 – when similar devices entered the country without formal clearance. Before making such products available worldwide, including here, the company skipped essential human testing altogether. That absence of trial work stands behind their entry into new regions like this one[25].

Over ninety-three thousand times, DePuy's version of ASR hips entered the body during replacements across continents[26]. Still, people started speaking after pain showed up too often. Trouble often followed those surgeries. Inside, contact between fake joint pieces grinds them down. Heat builds when surfaces rub hard against each other. That rubbing leaves marks – tiny particles that drift away. When an implant uses metal-on-metal, the rubbing parts create heat. That heat causes tiny metal bits to break free into the body fluid. These particles can trigger serious problems needing another surgery. Some researchers say blood with high amounts of cobalt or chromium may cause harm over time. It turns out these metals might damage areas inside the body. A review by Australia's TGA in 2007 showed the ASR Hip System needed replacement more often than most. Following poor results in 2009, Canberra stepped in, pulling the device from sale after stricter rules were introduced[27].

By late summer 2010, DePuy pulled every ASR model worldwide. A twist came in late December 2009: officials in India handed down a fresh approval letting the company sell these same implants. After that clearance arrived, by early January 2010, company lawyers stretched the old import permit further using the new license even though disaster loomed less than three months away[28].A tip from someone unknown led to a patient showing extreme side effects after using ASR hip devices, triggering action by Maharashtra FDA, who later filed a case against Johnson & Johnson in 2011. Attention then shifted to CDSCO, pushing officials to highlight problems with shoddy hip replacements while also stripping J&J of authority to bring such goods into the country. By April 11, 2012 – about three years past the first worldwide pull of the device – CDSCO made good on that move, officially cancelling import rights for the item. A complaint arrived from the Joint Commissioner at the Food and Drugs Agency, sparking CDSCO's move. Instead of responding properly, the company failed to warn patients about deep problems with the device. Serious flaws and harmful outcomes went unaddressed by the manufacturer. By late 2013, regulatory attention turned toward fixing the issue. On December 13, just issued, came an official warning from CDSCO – pull the faulty J&J hip implants from Indian markets. More than four thousand six hundred ASR operations unfolded across hospitals here. Yet follow-up records showed mere one quarter remained linked through proper channels. Even though there was no payment from the company in India, in America they settled on paying close to two point five billion dollars to about eight thousand people affected[29].

Back in 2017, the Health Ministry set up a panel of experts headed by Dr. Arun Kumar Agarwal – once Dean and Professor at Maulana Azad Medical College, known for his work in ENT – to look into issues tied to flawed ASR replacement surgery kits across India. Following that review, the group turned in a detailed summary pointing toward several steps: extending the ASR pay-out

scheme through to August 2025, actively working to locate every individual who'd gotten an ASR implant, along with financial support provided to anyone harmed by it[30].

Compensation:

Following the government's acceptance of the report's suggestions, a panel of national experts formed under Dr. R.K. Arya took charge. Their task? To determine fair compensation levels. Under the approved method, people who got broken implants prior to August 2010 might get as much as Rs.1.2 crore in return[31].At the same time, Mr. Goenka – living in Delhi – started legal action through a public interest lawsuit in the Supreme Court. His mother had been harmed by the flawed device, so he'd previously brought a personal grievance against Johnson & Johnson[32].Following advice from the Central Expert Committee, CDSCO asked J&J to compensate three individuals – two from Maharashtra at 74.5 lakh and 65 lakh – and another two from Uttar Pradesh at 1 crore and 90 lakh[33].

IN OTHER COUNTRIES:

Established in 2011, the International Medical Device Regulators Forum (IMDRF)which includes nations like the US, China, India, and Japan created the Medical Device Vigilance (Mv) program to standardize global regulations and track adverse events related to medical technology[34].

ADVERSE EVENTS REPORTING IN OTHER COUNTRIES:

The adverse events reporting of medical devices in Some Countries like the FDA requires that MDAEs must be reported by their manufacturers and importers, including quality problems, defects, and performance errors. Similarly, patients, users, and health professionals can voluntarily report the same in case of treatment failures to improve patient safety [35].

IN EUROPE:

The manufacturers report the MDAEs to the National Competent Authority (NCA) in Europe within two days, death reports and other worse health problems within ten days, and other non-serious incidents within 30 days. In contrast, health professionals report these to the NCA and the manufacturers[36].

✓ CASE STUDY: On failure of medical device called 'Essure'

Bayer AG is a German Multinational Pharmaceutical and Biotechnology Company and it is one of the largest pharmaceutical and biomedical company in the world. The Essure device, produced by Bayer, is a nonhormonal permanent birth control device and it does not require general anaesthesia with implantation process[37,38]. The device consists of two coils, an outer coil which is made of stainless steel and an inner coil made of a nickel titanium alloy. The coils are placed in the fallopian tubes, ultimately resulting in tubal occlusion [39]. The implantation procedure of Essure involves no incision and may be completed in ten minutes[38,40,41] . Until 2013, more than 750,000 Essure procedures were performed worldwide [42-44]. However, tens of thousands of women worldwide have suffered from adverse events associated with Essure which is very large number of people affected [45,46]. Reported adverse events include problems like persistent pain, perforation of the uterus and fallopian tubes, intra-abdominal or pelvic device migration, extra bleeding, and hypersensitivity reactions[41,42,45-48]. Some women needed the device surgically removed, and unwanted pregnancies due to Essure's failure are detailed in case reports [40,47,48].The first case of Essure tubal sterilization was conducted in Australia in 1999, then the use of Essure spread to the U.S. and

Europe [49].Nonetheless, some tragic cases were reported by the literature, and the first publication concerning unwanted pregnancies was published by Levy et al. in 2007 [50]. A study in 2015 found a 10-fold increased potential risk of re-operation in the first year for patients with Essure compared with patients who underwent laparoscopic sterilization [51].An uncommon but serious side effect of Essure is a nickel allergy, and the manufacturer claimed that 0.004% of Essure's users are likely to have hypersensitivity reactions to nickel [52]. As of 2018, only four previous case reports worldwide have suggested that nickel may cause allergic contact dermatitis. For the fourth case, the allergic symptoms were completely resolved after a hysterectomy [53].

Bayer was required by the U.S. Food and Drug Administration (FDA) to add a new boxed warning in 2016 and was also ordered to do post-marketing surveillance study comparing the adverse effects of the Essure and tubal ligation this indicates the need of Materiovigilance[43,54,55]. In February 2016, the FDA ordered Bayer to conduct a post-market safety study to help the FDA better understand the risks of Essure comparing with laparoscopic tubal ligation[43,56] . On October 31, 2016, the FDA issued the final guidance including a warning box of safety statement and a checklist for the decision making of permanent birth control choices. Bayer announced that they would continue to follow and implement FDA restrictions on Essure sales and distribution in the beginning of April 2018. On December 31, 2018, Bayer stopped selling or distributing the Essure devices in the U.S., but Essure could be implanted within one year after purchase [57,44]. As Bayer stated, the reason for their decision was that "the demand for Essure has fallen sharply in many markets recently, and this trend is not expected to change" [44,58]. In December 2018, the FDA approved a revised protocol to extend Bayer's mandatory follow-up study [44].

The general goal of these case studies is to indicate the need of testing of medical devices after the marketing of the product is done and to highlight the issues or problems caused by neglecting the post marketing surveillance of medical devices or we can say Materiovigilance. The first case study was about the ASR hip implant which is manufactured by the Johnson and Johnson company and the second case study was about the breast implants manufactured and distributed by Bayer company. These cases shows the need of Materiovigilance so that the adverse events can be reported timely and the proper actions should be taken by the company to resolve the problem.

IN CANADA: Health Canada reviews applications of new and remodelled or redesigned devices in Canada and requires that deformities be reported by the manufacturers and the consumers on their respective forms, depending on the device category. A potential death case should be reported to Health Canada within ten days, whereas a non-critical case should be within 30 days [59].

IN AUSTRALIA: Manufacturers and sponsors report per the guidelines set by the Therapeutic Goods Act (TGA) in Australia, and TGA maintains records containing a detailed history of all lots, components, and potential health hazards for a maximum of five years [60].

IN JAPAN : The MDAEs are reported by the marketing authorization holder (MAH) within two weeks, and any death events or critical cases are reported within 30 days in Japan [61].

IN CHINA: Likewise, China Food and Drug Administration (CFDA)'s National Centre for ADR Monitoring collects adverse event reports and manages postapproval surveillance in China, even at regional and provincial levels. Injury-related events should be reported to the local ADR monitoring centres within 15 days and death events to the National Centre. However,

manufacturers and distributors can also directly submit the reports to the National Centre in the country [62]. The need of adverse events reporting is to minimize or lower the risks, to ensure patient safety , to monitor the long term safety profile of medical devices post marketing.

NON REPORTABLE EVENTS:

Regulatory authorities often specify that not all adverse events require formal reporting. Key exclusions typically include:

- Even stemming from a patient's pre-existing health conditions.
- Incidents occurring after a product's shelf life has expired.
- Side effects clearly documented in the manufacturer's labelling.
- Untoward events caused by abnormal use or patient behaviour. ➢ Issues resulting from improper storage or handling by the user.
- Expected clinical outcomes that do not indicate product failure.
- Minor reactions that do not pose a significant health risk[63].

RECALL:

Devices are recalled for multiple reasons, some of which are defects in the products or their potential impacts on morbidity and mortality to the users [64]. The guidelines of Medicine and Healthcare Product Regulatory (MHRA) and GHTF stated that devices could be returned to their manufacturers or vendors as primary methods. Also, these can be alternatively subject to modification, remodelling, substituting of newer ones, or dismantling as part of a regular device recall [65].Regulatory authorities like the FDA or device manufacturers can recall the products when deemed to pose any health complications to the patients. Whenever the manufacturers even voluntarily recall the products, they should notify the FDA immediately. The FDA may recall devices based on their categories or severity of harm and may update its website with reasons of such recalls [66]. Class I recalls apply to the highest risks to patients, Class II recalls refer to those with a moderate risk, whereas Class III recalls meaning those with low-risk profiles [67].Some recent events which leads to product recall are: On October, 2021in USA the Ellume COVID-19 home test shows False-positive test results[68].On July, 2020in India the Coronavirus testing kits gave non-performance reports from Punjab, Rajasthan, and Karnataka[69].On October, 2019in USA the Medfusion® syringe pumps therapyrelated malfunctioning alarms related to battery[68].On July, 2019 in USA the Allergan breast implant cause high risk of anaphylactic large cell lymphoma[70].

CONCLUSION

Materiovigilance (Mv) systems are already in place in several developed nations such as theUK, USA, New Zealand and Australia amongst other countries and in developing nations Such as China and India to monitor and report adverse events associated with medical Devices. Nevertheless, not all countries with a low and middle-income status have a powerful manufacturing background, significantly depend on the imported medical devices, and do not Have a properly organized materiovigilance system established yet. This is an issue to be concerned about, because it exposes patients to avoidable damages. To counter this, it is the paramount requirement that the policymakers assume earnest measures in designing Materiovigilance schemes, and motivating both medical professionals and patients to report Adverse events that are related to the use of medical devices without any fear or doubt, and to also ensure that patients get clear information about medical devices, the risk in using such

Products and the occurrence trends of the risks as stated in the package inserts of medical Devices. Materiovigilance systems are currently in the initial phases of development even though the pharmacovigilance systems throughout the world have made remarkable Advances. Thus there is an urgent need that the policy makers should undertake powerful actions towards creating materiovigilance systems, having medical device safety as a serious Concern as it is with pharmaceutical safety.

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