Review Article

Navigating the Landscape of Medical Device Failures: Challenges, Regulations, and Materiovigilance

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ABSTRACT

Introduction: *In the realm of healthcare, the significance of materiovigilance cannot be overstated. Materiovigilance, a term often overshadowed by pharmacovigilance, focuses on the surveillance and control of medical devices' safety and performance post-marketing. Its components include the systematic collection, analysis, and interpretation of data related to medical devices, aiming to enhance patient safety by decreasing adverse events associated and optimize device efficacy*

Methodology: *This literature review utilized databases like PUBMED, EMBASE, SCOPUS, and COCHRANE, employing keywords such as "materiovigilance"; "pharmacovigilance" ;"materiovigilance history"; and "awareness about materiovigilance"*

Results: *Critical components like vigilance reporting systems, risk assessment, and regulatory interventions play a pivotal role in ensuring medical device safety. It is evident that a significant lack of awareness, posing risks to patient safety. This research serves as a tool to bridge the awareness gap, emphasizing the need for understanding and active participation in Materiovigilance*

Conclusion: *Collaborative efforts among regulatory bodies, healthcare providers, and manufacturers can enhance understanding and awareness in Materiovigilance. This clarity and collaboration contribute to fostering Materiovigilance awareness, ensuring improved patient safety. By creating awareness, we aim to establish a safer healthcare environment, guaranteeing the efficacy and safety of medical devices globally.*

Keywords: *Materiovigilance, medical devices.*

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INTRODUCTION

From Mesmer's Magnets to Modern Challenges: Unraveling the History of Defective Medical Devices"

Unquestionably, basic medical tools have been around for eons. Examples include wooden splints to hold broken bones in place, homemade stretchers to hold the ill, and creative crutches. Numerous historical writings and archaeological sites have offered copious evidence supporting their use. For instance, John Graham of England is credited with popularizing the "celestial bed," a device that was linked by electric coils and used to treat sterility, in 1745. This is where the practice of making inflated medical claims about mechanical and electrical devices originated.

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During the 1700s, Franz Anton Mesmer's instruments—who had arrived in Paris in February 1778—were arguably the most well-known. According to Mesmer, "animal magnetism" is the primary force of nature and the foundation of all wellbeing[1]. Mesmer claimed that patients might be healed by attaching them to specifically magnetized water jars and recharging them with animal magnetism using magnets and, later, enormous tubs in which iron rods were affixed. After conducting studies, the Royal Commission, which was assembled by the elite of medicine and included notable scientists like Benjamin Franklin and Antoine Lavoisier, declared in 1784 that Mesmer's treatment was ineffective. Towards the end of the 1700s, Dr. Elisha Perkins invented the first well-known fake medical equipment to be sold in the United States. Perkins created two roughly 3-inch-long brass and iron poles that were known as "Perkins" Patent Tractors[1]. He claimed they could eradicate any illness from the body and sold them all over the world. After ten years, it was discovered to be a fraud.

In the United States, legislation to control the adulteration and misbranding of food and medicine was the focus of governmental and public attention during the 1800s, but not of medical equipment. During this time, a variety of medical devices flourished. During this time, one of the most often used deceptive devices was the Abrams "dynamizer" computer[1]. Abrams contended that he could identify the specific sickness the patient had contracted and pinpoint the precise body area where the illness was concentrated by injecting a blood sample into the system. Abrams' machine was exposed as a fraud by the time of his death in 1924.

With all of this data, one could easily draw the conclusion that defective medical equipment and the bad outcomes they cause have existed for hundreds of years. The 21st century saw the publicizing of numerous case reports. A global inquiry revealed that despite being labeled as dangerous, a number of medical gadgets were still being sold in international marketplaces. In addition to more than 1.7 million recorded injuries globally, the usage of these dangerous medical equipment has been linked to more than 83,000 recorded deaths in the previous 12 years[2]. Incubators, pacemakers, breast implants, contraceptives, and artificial hips grafted into patients' bodies are some of the most common and hazardous medical devices that have led to unfavorable results.

A 60-year-old man was the subject of an incredibly uncommon occurrence of implanted cardioverter defibrillator malfunction that was documented in 2002. He was fitted with his initial implanted cardioverter defibrillator (ICD) in 2002; however, the device model was replaced in 2012 without any issues[3]. At his 6-month check-up in wireless interrogations, it was discovered that there was no longer any communication with the ICD. Every time the doctors attempted to interact with the ICD, the patient received numerous shocks via ECG telemetry. Despite the patient's eventual recovery, a new generator that was linked to lead had to be installed[3].

Similar to this, a significant event occurred in 2010 when "Johnson and Johnson," a reputable pharmaceutical company, was forced to backload all of their ASR XL

Acetabular hip replacement systems (metal-on-metal). When metallic debris, particularly from metal implants, leaked into the circulation, patients had to have many procedures. Patients also experienced discomfort from friction while using a prosthetic ball and socket[4]. The authorities decided to implement a global recall in response to the uncontrollably increasing number of cases that were identical. ASR implants similar to this one were recalled in India because they were malfunctioning. A 44-year-old man who had experienced irregular heartbeats, visual problems, and trouble walking was one of the patients of this defective medical gadget[3]. It was stated that a Johnson and Johnson medication business replacement hip that was inserted was the cause of all of these incidents. The Health Ministry of India established an expert committee in 2017 to assess and look at all the problems that were reported as a result of the implants because the number of cases was growing at an alarming rate[3].

Manufacturers of medical equipment and medical professionals have long claimed that spinal cord stimulators are a wonder treatment for the millions of people suffering from a wide range of excruciating ailments. These devices are promoted as a treatment option for persistent pain in the elderly and as a substitute for drug addiction. However, the number of injury cases makes up the third-highest percentage of incidences involving medical conditions. Since 2008, the FDA has been informed of over 80,000 similar incidents. Patients have reported that they were burned, electrocuted, or had paraplegia, according to FDA records. Insulin pumps and metal hip replacements were the two devices with the highest number of reported injury cases.

The FDA issued a recall of implanted cardioverter defibrillators (ICDs) that was comparable to the Johnson & Johnson hip implant recall [9(a,b,c)]. Electrical failures were caused by partially exposed aluminum wires as a result of a manufacturing flaw. The capacitor was more likely to experience an electrical fault when the wires were improperly insulated. This resulted in problems with high voltage therapy administration. 350,000 patients worldwide were using this device prior to the 2016 recall. In one tragic situation involving an implanted defibrillator in the United States, the family of a 27-year-old woman filed a lawsuit after St. Jude Medical called the device back due to a battery issue[5].

MEDICAL DEVICE ILLUSTRATION AND THE RISE OF MATERIOVIGILANCE (MV)

In the realm of health care, medical devices play a crucial role in the diagnosis, prevention, and treatment of various medical illnesses and disorders, much like pharmaceuticals and medicines do. A medical device is defined as any apparatus, machine, implant, IVD, software, or assisted material that is intended to be used alone or in combination with humans for one or more medical purposes, such as disease or injury diagnosis, prevention, treatment, monitoring, or investigation, replacement, modification, treatment, monitoring, and support of an anatomical or physiological condition for life support, in vitro examination control over conception, or intended action by pharmacological, immunological, or metabolic in or on of human body[6].

Products range widely, from inexpensive bandages to expensive CT or MRI machines that require constant maintenance. The use of medical equipment is greatly increasing. It is therefore essential to guarantee their effectiveness and quality. But device quality varies, and in clinical settings even the best devices might malfunction. Furthermore, these technologies might also result in safety problems that inadvertently endanger the patients. Post-marketing surveillance, which aids in assessing device performance and prioritizes safety, is therefore essential to resolving these problems[7]. In addition to post-marketing surveillance, medical device harmonization is also required[8]. The primary goal of harmonization is to stimulate international demand and scientific innovation by energizing the merger of regulatory practices related to ensuring the quality, efficacy, performance, and safety of medical equipment.

Different nations have their own set of rules and regulations. In 1992, five countries—the United States, Canada, Japan, Europe, and Australia—joined the Global Harmonization Task Force (GHTF)[8] in an effort to promote consistency between national medical device regulatory systems as well as efficacy and safety.

The detection, evaluation, monitoring, and management of adverse drug reactions (ADRs) or adverse events (AEs) associated with specific pharmaceutical products are the focus of the pharmaceutical sciences field of pharmacovigilance (PV). To keep track of unfavorable incidents involving medical equipment, the International Medical Device Regulators Forum (IMDRAF) was founded in 2011. The objective was to expedite the convergence and harmonization of global medical device regulations. Ten nations, including South Korea, Japan, China, India, the United States, and the European Union, were members of this international organization[10]. As a result, materiovigilance (MV) was introduced.

MATERIOVIGILANCE

Materiovigilance envisages close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting with estimate of undesirable occurrences and reacting to them with field safety corrective actions or device recall during post -marketing phase of a medical device[11].

MV's regulating bodies in nations are -

- USA-Food and Drug Administration (USA-FDA) in USA
- European Medicine Agency in Europe
- Food and Drug administration (CFDA) in China
- Ministry of Labor, Welfare, and Health (MHLW)in Japan
- Therapeutic Good Administration (TGA) in Australia
- Health Canada in Canada
- CDSCO in India

MVPI (MATERIOVIGILANCE PROGRAM OF INDIA)

The Indian Drugs and Cosmetic Act was utilized to regulate medical devices, and there was no mechanism in place earlier for tracking unfavorable results related to them. Later, the Indian Health Ministry implemented strict measures to lower the adverse drug reactions (ADRs) associated with these devices in response to a marked rise in the number of hospitalization and death cases brought on by subpar equipment, such as defective hip implants and cardiac stents. In July 2015, the health ministry approved the Indian Pharmacopoeia Commission (IPC) to function as the National Coordination Center (NCC) for the development of a materiovigilance program[12]. The MvPI was formally launched on July 6, 2015, with the support of Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) as the National Coordinating Center (NCC). Later, in 2018 onward, the Indian Pharmacopoeia Commission (IPC) functions as NCC for MvPI besides as NCC for PvPI.

Materiovigilance envisage close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which can identify, collecting, reporting with estimate of undesirable occurrences, and reacting to them with field safety corrective actions or device recall during post -marketing phase of a medical device[11].

The MvPI aims at:

1. Creating a countrywide plan for monitoring patient safety
2. Examining the benefit–risk ratio related to a medical device
3. Creating evidence-based data for medical equipment associated with adverse events
4. Supporting the Central Drugs Standard Control Organisation (CDSCO) in making decisions about medical device regulation in the country
5. Exchanging safety-based information with various stakeholders in the industry
6. Collaborating with other health-care organizations and international agencies for information exchange and data management[11].
7. Various Centers under the Indian Materiovigilance Program

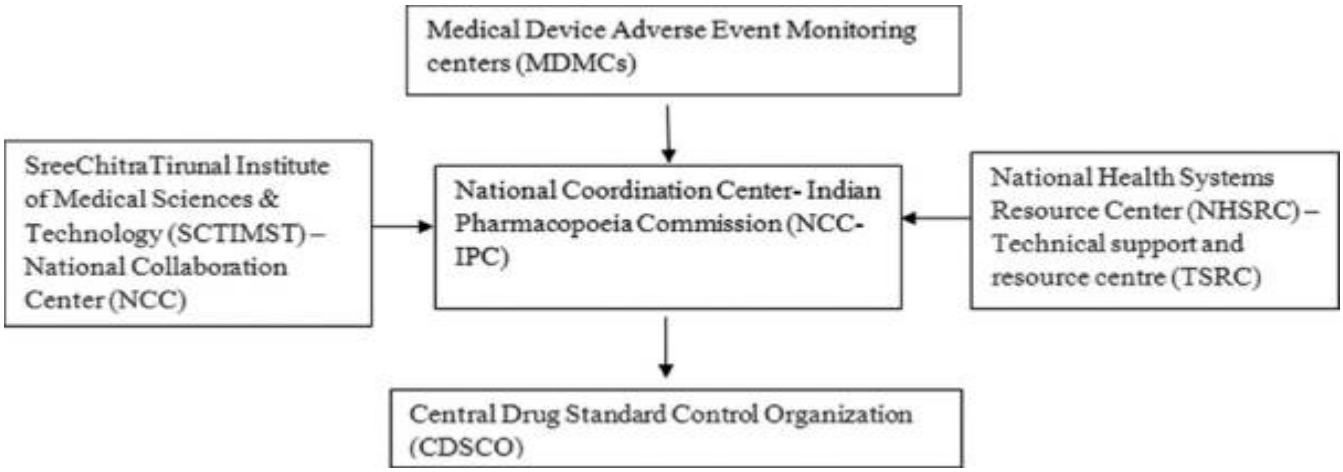

Figure 1: Organizational Structure of MvPI

Under MvPI, a total of 150 medical device-related adverse events (MDAEs) have been reported, up from the initial 10 MDMCs that were recognized nationally. The reporting rate has also gone up since the Program's inception. Through MvPI, over 7000 reports have been sent to the IPC. Any suspected or proven MDAEs that fall into one of five categories—not linked, unlikely, plausible, probable, or causal relationship—must be properly identified, gathered, and reported by the MDMCs. Each month, MDMCs shall forward the reported instances to NCC-IPC for evaluation and investigation. Five working days are the deadline for reporting an MDAE after becoming aware of it, and thirty calendar days are allowed for reporting the incident after determining its underlying cause. The exclusive keeper of the MvPI database is IPC. The NCC is in charge of liaising with all MDMCs in India and informing the CDSCO of any pertinent issues. Furthermore, they work in conjunction with foreign authorities and offer financial assistance to MDMCs, the National Health Systems Resource Centre (NHSRC), and SCTIMST. Serving as the National Collaboration Center, SCTIMST offers assistance with any technical issues.

NHSRC participates in the Programme as a technical support partner. In order to prepare standard operating procedures, guidance documents, newsletters, training manuals, etc., it offers technical support and guidance. Ultimately, all of the concerns are brought to the attention of the CDSCO, a national regulatory body that oversees safety. It is in charge of carrying out all desired activities in response to the NCC-MvPI's recommendations[11]. The organizational structure of MvPI is presented in Figure 1.

MvPI seeks to align the vigilance system with GHTF members by doing the following:

In order to address public health protection, it promotes convergence at the worldwide level in the regulatory system evolution for devices, protecting all the rights of contributing members[21]. India works with the Global Health Task Force (GHTF) in order to improve access to information on some of the primary medical device regulatory systems[22].

Adopting a unified nomenclature for medical equipment will benefit from it.

- Devices will only be approved by heavily regulated markets.
- There will be a vast network for post-marketing vigilance.

REPORTING ADVERSE EVENTS FROM MEDICAL EQUIPMENT (MDAE)

Adverse occurrences connected to medical equipment are reported through a variety of channels. Events can be recorded that are significant, non-serious, frequent, uncommon, known, or unknown, but they must be relevant to the ADR. here is a MDAE (Medical Device Adverse Event) reporting form in which reporting of any medical device associated adverse events may be reported[13]. This form consists of initial description, details of the adverse event occurred, and associated risks to the patient. It can be downloaded from the website of the IPC. Adverse events can also be reported by PvPI (Pharmacovigilance Program of India) helpline number[11]. Any suspected serious adverse events must be reported to CDSCO and commission within 15 calendar days from the occurring of an event. After filling the MDAE form, it can be directly submitted to either the SCTIMST or the NCC.

CHALLENGES IN REGULATING MEDICAL DEVICES ASSOCIATED ADVERSE EFFECTS

The basis of the interaction between policy and creativity is mutual control. Clear and effective regulations govern the mechanism of innovation in a particular field. Ensuring enhanced patient safety should be the primary concern with regard to medical devices and the currently being discussed regulatory modifications.

"INNOVATION'S BLIND SPOT: THE CONSEQUENCE OF INSUFFICIENT TESTING IN NEW, TRANSPARENT MEDICAL TECHNOLOGIES"

Transparent innovation is a popular trend in a variety of industries, including the medical device industry. Open

innovations have become the dominant model for connecting developing technologies and markets. The need for medical equipment is increasing irreversibly in tandem with advancements in other industries and medical processes, as evidenced by several research papers and data sets. These trends strongly imply that effective solutions to this issue are needed. According to Peter et al, open invention frameworks enhance value by incorporating multiple new ideas into a variety of external principles[17]. All organizational units must collaborate in order to maximize results in every area, improve performance, and streamline available procedures. This entails encouraging a positive culture of teamwork, being receptive to new information and the sharing of expertise, as well as having a drive for innovation, change, and new inventions in the workplace. The primary issue that has the ability to fundamentally alter organizational growth is the fact that the new standards were created with patient protection in mind. On the other hand, it is evident that improving the existing regulations will improve the performance of an organization. Raising the stakes with tens of thousands of crowns at stake frequently indicates a greater requirement for monitoring and testing.

When a commodity in business danger class III is used, significant costs are frequently incurred over its lifetime. Clinical testing, the most costly component, would need to be repeated frequently using these kinds of medical supplies. In actuality, during the last ten years, a lot of businesses have discussed how to handle this shift, and occasionally this has led to conflicting prospects, especially for small and medium businesses. Choosing budget-management options entails changing the medical equipment to fall into a lower risk category in order to completely change the components that contribute to the development and progression.

All things considered, the disciplines of science, law, and healthcare are very responsive, and many human achievements and study areas—such as economics, law, and services pertaining to health policies—overlap. The collaboration between national regulatory authorities and medical device developers is essential for innovation and competition in this industry. The procedure for adopting novel medical equipment is typically more difficult than it is for standardized products.

It becomes more difficult to determine new technologies' safety, assess their usability, determine their potential usefulness to patients, and take into account a host of other factors the more inventive they are.

"INCOMPLETE PICTURE: HOW UNDERREPORTING HINDERS THE QUALITY CHECK OF MEDICAL DEVICES"

In fact, there is a growing concern about quality in the fields of medicines, medical diagnostics, and medical equipment and technologies. A decrease in the quality of medical devices would inevitably lead to a number of unfavorable outcomes, such as fatalities, protracted hospital stays, congenital defects, and other types of disabilities. Improving the quality and safety of medical devices is crucial for lowering this, and reporting adverse events plays a major part in that. The main issue that all nations deal with when it comes to reporting adverse events related to medical devices is the underreporting of these incidents. The regulatory bodies put rules and directives on manufacturers to oversee the reporting procedure. Many businesses underinvest in this area, which results in subpar adverse event reporting to regulatory agencies. This has a serious impact on both quality and patient and medical device safety. Furthermore, when manufacturers submit medical device reports to regulatory bodies, the language used in them is frequently vague or mislabeled, making it difficult for the authorities to comprehend and approve the reports. Industries should accurately state in their MDR submissions whether any deaths or injuries have occurred. Even in cases where a death has happened, they frequently label it as a simple malfunction, which obscures the actual outcomes of the incident.

"SILENT SHADOWS: UNRAVELING THE CAUSES OF UNDERREPORTING IN MEDICAL DEVICE ISSUES"

The primary causes of underreporting adverse events include ignorance, a lack of ADR monitoring centers, and a lack of reporting funding from businesses. People still don't understand what reporting is or how it's done, and they frequently dismiss all of the negative user events that take place. Not only do individuals not know how to report an adverse event (AE), but many healthcare professionals do as well, particularly in less regulated or non-regulated nations. ADRs are also not reported as often since ADR monitoring centers are not situated in many locations.

It is widely accepted that ensuring the safety and high quality of medical equipment requires an efficient, proactive surveillance system. All of these initiatives also have the potential to improve patient safety and the healthcare system. Educating stakeholders about the importance of MDAE reporting is one of MvPI's main objectives. There are comparatively few KAP surveys on materiovigilance compared to the numerous KAP research on pharmacovigilance among medical workers. According to Tudy and Meher BR et al., seniority does not influence one's level of materiovigilance awareness. Because materiovigilance is a relatively new concept and is not as heavily emphasized in the curriculum, it may be the cause of the lack of awareness also it does not come easily in the conscience of doctors. Busy schedule is also one of the reason for negligence in reporting. However, Gagliardi *et al*.[20] observed contrarian attitude, they had found that medical professionals considered reporting of adverse events associated with medical devices as unnecessary and pointless. They also did not perceive the reporting of adverse events as their responsibility.

CONCLUSION

Over the last few years, medical professionals worldwide have observed a high frequency of use of medical devices. It is true that national macrovigilance programs are commendable attempts to guarantee the security of medical equipment in use. Its rigorous application has addressed both human welfare and the safety of medical equipment. In order to ensure that a medical device is safe, effective, and performs well enough to be sold and improve community health, regulation of medical devices is essential. Customers' trust and confidence in the device will naturally increase if it is safer and more effective. As the assessment pointed out, gadgets are categorized according to the risks they pose, and as such, reporting and regulation of them must be done.

The adverse event reporting form for medical devices is currently only available in English in some countries. However, this may become available in multiple languages in the future. This issue is particularly prevalent in nations like India, where many different languages are spoken. It should therefore be provided in all languages that are spoken in order to increase patient engagement in reporting. Value will become more important in the upcoming years, and it won't just be about the gadget. By 2030, medical gadgets will actively contribute to value creation on a worldwide scale by interacting with consumers and patients. This will likely necessitate a shift from cure and therapy to prevention through astute solutions and services that will improve outcome.

Manufacturers, government agencies, medical practitioners, and patients/caregivers must cooperate closely for a materiovigilance program to be successful. In order to maintain patient safety and the materiovigilance program, it is imperative that any adverse events associated to devices are appropriately reported. A benefit-risk ratio will be established as a result of the ongoing collection of adverse reactions and the signal detection procedure, which will assist provide data about the dangers and advantages of the devices. Since materiovigilance is a continuous process, the information gathered over time will assist patients and healthcare providers in making more educated decisions. Prescribers will be more knowledgeable and aware of the anticipated side effects, which will stop similar incidents from happening again. This will lessen the healthcare system's burden from device-related morbidity and death.

Physicians had an optimistic attitude despite their lack of awareness and practice. But there was a lack of attitude and knowledge transition when it came to reporting MDAE. A positive outlook implies that, with the right work, enhancing medical device oversight and the valuable contribution of physicians to the system can easily improve society's healthcare system. To encourage doctors to report spontaneously and fortify the nation's health and welfare system, it is necessary to hold frequent seminars, workshops, CMEs, and training sessions, as well as to integrate materiovigilance into undergraduate or graduate curricula and make reporting practical and simple at work. There is a need of encouraging "safe device handling after implant" sessions because a lesser number of practising doctors have ever been a part of it till now, which is restraining them to prevent any mislead, if it tend to occur. Hence, the authors believe that creating awareness among all medical personnels altogether irrespective of age or designation is need of an hour, for the goodness of patients and healthcare sector of the state.

THE ROLE OF SOCIAL MEDIA IN MATERIOVIGILANCE

Social media platforms such as LinkedIn, Facebook, Twitter, and YouTube facilitate the dissemination of timely and accurate information to users regarding rational selection and undesirable events. They also serve to promote discoveries and issues pertaining to science and health. If any flaws are discovered, they also help spread the word about recalls of medical devices. In the end, this will inform practitioners and users on the most recent regulations or activities pertaining to the item. However, users risk physical and mental harm if they rely too much on information shared on social networking platforms for all of their information needs. Because false information can sometimes be worse than no information, it is crucial to critically analyze content published on social media and verify its source in order to prevent potential misinformation.

HEALTH PROFESSIONALS' ROLE IN REPORTING ISSUES RELATED TO DEVICES

Building and strengthening individual and institutional capacity to report and address the harmful effects of medical devices is one way that health professionals, including surgeons, doctors, nurses, and pharmacists, can address concerns associated to these devices. The database information system that creates signals for medical equipment can help with this. If a flaw should arise in a device, they can also instruct and train coworkers and patients to emphasize the significance of Mv in device recalls. After all, the most important objective is to start and cultivate an institutional culture for reporting MDAEs in order to prevent them in the future.

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