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Strengthening Medical Device Safety Through Regulations and Materiovigilance

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Abstract:
Materiovigilance is essential in contemporary healthcare, safeguarding the safety and efficacy of medical devices post-market release. While sometimes eclipsed by pharmacovigilance, materiovigilance is dedicated to the identification, analysis, and prevention of device-related adverse events by systematic data collection and assessment. The primary objective is to safeguard patients by early identification of dangers and ensuring the effective and safe operation of medical devices in practical environments. This study aims to emphasize the fundamental elements of materiovigilance and draw attention to the considerable lack of awareness regarding this crucial yet underappreciated facet of healthcare. A thorough literature search was performed utilizing databases such as PubMed, Embase, Scopus, and Cochrane, employing keywords like "materiovigilance," "pharmacovigilance," "materiovigilance history," and "awareness of materiovigilance." Relevant papers were analyzed to discern patterns, deficiencies, and fundamental issues. The findings demonstrate that essential components, including comprehensive reporting systems, systematic risk assessment, and stringent regulatory control, are fundamental to guaranteeing medical device safety. Notwithstanding these established systems, a significant lack of knowledge endures among healthcare personnel and stakeholders, heightening the risk of underreporting and jeopardizing patient safety. This analysis underscores the necessity of addressing this deficiency by education, training, and coordinated participation in materiovigilance activities. Enhancing knowledge and promoting active engagement among regulatory authorities, healthcare practitioners, and manufacturers can substantially improve materiovigilance procedures. Collaborative initiatives will enhance the safety of healthcare environments and guarantee the efficient and dependable utilization of medical equipment globally.

Keywords: Materiovigilance, Medical device safety, Adverse event reporting, Risk assessment, Regulatory oversight, Patient safety.

Introduction

Indubitably, fundamental medical instruments have been in existence for ages. Initial instances comprise wooden splints for fracture stabilization, handcrafted stretchers for patient transport, and makeshift crutches. A plethora of historical documents and archeological evidence corroborate their enduring usage. In 1745, John Graham of England unveiled the "celestial bed," an electrically augmented apparatus purported to remedy sterility—one of the earliest instances of inflated medical assertions regarding mechanical and electrical equipment (Graham, 1745). In the late 18th century, Franz Anton Mesmer's

apparatus gained considerable recognition. Mesmer posited that "animal magnetism" regulated nature and health, asserting that patients might be healed by linking them to particularly magnetized water vessels or big tubs equipped with iron rods (Mesmer, 1778). In 1784, a Royal Commission including Benjamin Franklin and Antoine Lavoisier determined that Mesmer's therapies were useless (Franklin & Lavoisier, 1784).

During the same era in the United States, Dr. Elisha Perkins unveiled the deceptive "Perkins Patent Tractors," brass and iron rods promoted as effective in eliminating sickness. Subsequently, they were revealed to be a fabrication (Perkins, 1796). In the 1800s, public and governmental scrutiny in the U.S. concentrated on the adulteration and misbranding of food and medications, but the regulation of medical equipment remained insufficient. This facilitated the proliferation of dubious gadgets such as the Abrams "dynamizer," which misleadingly asserted the capability to identify diseases from a blood sample. By 1924, this apparatus was also demonstrated to be false (Abrams, 1924). These historical instances demonstrate that flawed or deceptive medical equipment have existed for an extended period. In the 21st century, international inquiries disclosed that dangerous medical equipment persisted in being sold despite acknowledged hazards. In the last 12 years, dangerous medical devices have been associated with approximately 1.7 million injuries and more than 83,000 fatalities globally (Global Investigation Report, 2018). Devices often associated with issues including pacemakers, incubators, breast implants, contraception, and artificial hips (WHO, 2019).

A unique incident included a 60-year-old male whose implanted cardioverter defibrillator (ICD) had a malfunction. Systematic wireless interrogation indicated a communication breakdown and recurrent shocks. Despite the patient's recovery, generator replacement was necessary (Patel et al., 2002). In 2010, Johnson & Johnson recalled its ASR XL Acetabular metal-on-metal hip systems owing to metal particles contaminating the circulation and resulting in tissue injury (Johnson & Johnson, 2010). The increasing incidence of infections prompted a worldwide recall, encompassing India. A 44-year-old Indian male patient had eye impairments, gait abnormalities, and heart irregularities associated with the defective implant (Health Ministry of India, 2017). Spinal cord stimulators, marketed as remedies for persistent pain, have also inflicted considerable damage. Since 2008, the FDA has documented more than 80,000 injury reports, encompassing burns, electric shocks, and instances of paraplegia (FDA, 2018). Insulin pumps and metal hip replacements significantly impact injury statistics (FDA, 2018). The FDA announced a significant recall of implanted cardioverter defibrillators owing to manufacturing problems, including exposed metal wires and inadequate insulation, resulting in electrical malfunctions (St. Jude Medical, 2016). Prior to the recall, around 350,000 patients globally were utilizing the device. A significant U.S. case was a 27-year-old woman whose family initiated legal action following the recall of a device due to a battery malfunction (St. Jude Medical, 2016).

Device Category	**Reported Injuries (approx.)**
Metal-on-Metal Hip Implants	200,000
Insulin Pumps	150,000
Spinal Cord Stimulators	80,000
ICDs & Pacemakers	45,000
Surgical Mesh (Urogynecological)	35,000

Table 1: Showing device category and their reported risks.

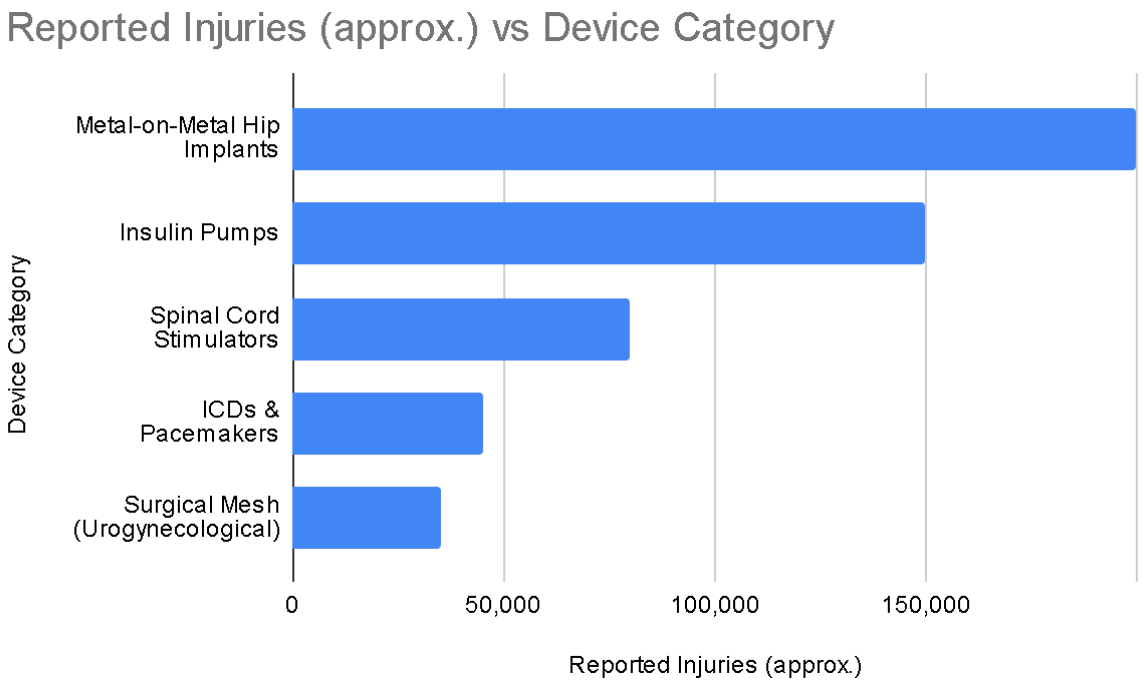

Figure 1: Global trends in Medical Device Adverse Events (2008-2024)

This review provides a unique historical-to-contemporary analysis of medical device failures, demonstrating that device-related injuries have endured for centuries despite advancements in technology. This study diverges from traditional discourse centered on contemporary regulatory challenges by examining hazardous gadgets from the 18th century to the present, uncovering persistent patterns of overstated assertions, insufficient regulation, and patient jeopardy. The analysis underscores how institutional deficiencies persistently jeopardize patient safety by amalgamating recorded historical frauds with contemporary worldwide recall data and empirical case studies. The paper emphasizes the urgent necessity for effective materiovigilance, illustrating that historical and contemporary device failures stem from inadequate regulation, poor stakeholder knowledge, and postponed corrective measures.

Modern Materiovigilance Insights

In healthcare, medical devices are essential for the diagnosis, prevention, and treatment of many illnesses and disorders, akin to medications. A medical device is characterized as any apparatus, machine, implant, in vitro diagnostic (IVD), software, or material designed for standalone or combined use for medical objectives, including diagnosis, prevention, treatment, monitoring, or investigation of disease or injury; alteration or replacement of anatomical structures; life support; in vitro examination; or contraception, without exerting its primary effect through pharmacological, immunological, or metabolic mechanisms (WHO, 2016). Medical equipment vary significantly, from basic bandages to sophisticated CT and MRI scanners that require ongoing care. The fast proliferation of medical technology necessitates the assurance of the safety, efficacy, and quality of these products. Even optimally designed equipment may fail in clinical environments, endangering patient safety. Consequently, post-marketing surveillance is essential for assessing device efficacy and detecting safety issues (Singh & Rao, 2017). Furthermore, the

harmonization of medical device legislation internationally is crucial for maintaining uniform quality and safety standards (Kumar et al., 2015).

Various nations adhere to distinct regulatory regimes. In 1992, the United States, Canada, Japan, Europe, and Australia established the Global Harmonization Task Force (GHTF) to advance international consistency in medical device standards and enhance device safety and efficacy (GHTF, 1992). Pharmacovigilance primarily emphasizes the identification, surveillance, assessment, and prevention of adverse drug reactions (ADRs). In response to the increasing incidence of device-related adverse events worldwide, the International Medical Device Regulators Forum (IMDRF) was founded in 2011 to expedite the harmonization of international medical device laws. The founding members comprised eleven significant regulatory regions, including Japan, China, South Korea, India, the United States, and the European Union (IMDRF, 2011). This global initiative established the groundwork for the idea and execution of materiovigilance.

In India, medical devices were traditionally governed under the Drugs and Cosmetics Act, and there was no specific framework to oversee adverse occurrences associated with these devices. An alarming increase in hospitalizations and fatalities associated with inferior devices—such as defective cardiac stents and hip implants—compelled the Health Ministry to enhance regulatory control (Sharma & Gupta, 2014). In July 2015, the Indian Pharmacopoeia Commission (IPC) was appointed as the National Coordination Centre (NCC) to spearhead the establishment of a systematic materiovigilance program (IPC, 2015). The Materiovigilance Programme of India (MvPI) was inaugurated on July 6, 2015, with assistance from the Sree Chitra Tirunal Institute for Medical Sciences and Technology (MvPI, 2015).

Metrovigilance and its centres

Materiovigilance entails the systematic surveillance of any adverse performance issues, malfunctions, or variations in the attributes of a medical device. It operates via a systematic framework that identifies, collects, analyzes, and reports adverse events or device-related issues throughout the post-marketing phase. The main goal is to implement prompt remedial measures—such as field safety notifications, corrective and preventative actions (CAPA), or device recalls—to safeguard patient safety (Smith et al., 2011).

Worldwide, materiovigilance operations are regulated by several governmental agencies. Principal regulatory authorities comprise:

- United States: Food and Drug Administration (FDA)
- Europe: European Medicines Agency (EMA)
- China: China Food and Drug Administration (CFDA/NMPA)
- Japan: Ministry of Health, Labour, and Welfare (MHLW)
- Australia: Therapeutic Goods Administration (TGA)
- Canada: Health Canada
- India: Central Drugs Standard Control Organization (CDSCO)

The Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) originally functioned as the National Coordinating Centre (NCC) for the Materiovigilance Programme of India (MvPI), after which the Indian Pharmacopoeia Commission (IPC) took over this responsibility in 2018, serving as the NCC for both MvPI and the Pharmacovigilance Programme of India (PvPI). Materiovigilance entails the systematic oversight of adverse performance issues, malfunctions, or variations in the attributes of a medical device via a structured system designed to identify, collect, assess, and report device-related

adverse events, while also implementing appropriate field safety corrective actions or device recalls during the post-marketing phase. The principal objectives of MvPI are to create a national framework for monitoring patient safety related to medical devices, to evaluate the benefit-risk profile of medical devices utilized in clinical practice, and to produce evidence-based data on adverse events to inform regulatory decisions and improve patient safety.

Under the Materiovigilance Programme of India (MvPI), the number of Medical Device Adverse Event Monitoring Centers (MDMCs) has significantly increased from the original 10 centers, with over 150 medical device-related adverse events (MDAEs) reported and more than 7,000 reports submitted to the Indian Pharmacopoeia Commission (IPC) since the program's establishment. MDMCs are tasked with detecting, collecting, and reporting all suspected or proven MDAEs, categorized as not connected, improbable, plausible, probable, or causative. Reported incidents must be submitted to the National Coordination Centre at IPC (NCC-IPC) monthly for assessment, with a need to report an MDAE within five working days of awareness and within thirty days after identifying its root cause. IPC functions as the only curator of the MvPI database and facilitates countrywide contact with MDMCs, concurrently notifying the Central Drugs Standard Control Organization (CDSCO) of noteworthy discoveries. Furthermore, IPC partners with global organizations and offers financial assistance to MDMCs, the National Health Systems Resource Centre (NHSRC), and the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST). SCTIMST, serving as the National Collaboration Center, provides technical help, whilst the NHSRC acts as the Program's technical support partner, aiding in the formulation of standard operating procedures, guidelines, newsletters, and training manuals. All significant safety concerns are elevated to the CDSCO, the national regulatory body tasked with executing the NCC-MvPI's recommendations. MvPI seeks to synchronize India’s vigilance system with Global Harmonization Task Force (GHTF) standards by fostering global convergence in regulatory practices, enhancing access to international regulatory information, promoting the adoption of standardized medical device nomenclature, ensuring device approval in highly regulated markets, and creating a comprehensive post-marketing surveillance network.

Reporting medical device adverse events

Reporting medical device adverse events (MDAEs) can transpire through several pathways and may encompass major, non-serious, frequent, uncommon, known, or previously undiscovered incidences, as long as they pertain to device-related adverse consequences. The principal instrument for documentation is the Medical Device Adverse incident (MDAE) reporting form, which records an initial account of the incident, device specifications, patient implications, and related hazards (IPC, 2013). This form may be downloaded from the Indian Pharmacopoeia Commission (IPC) website. Adverse occurrences can also be reported via the Pharmacovigilance Programme of India (PvPI) hotline (PvPI, 2011). Any suspected significant adverse event must be notified to the Central Drugs Standard Control Organization (CDSCO) and the IPC within 15 calendar days of its occurrence. Upon completion of the MDAE form, the report may be sent directly to the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) or to the National Coordination Centre (NCC) at IPC for subsequent examination and regulatory measures.

Challenges in Regulating Medical Devices Associated Adverse Effects

The interplay between regulatory policy and technical innovation is based on reciprocal oversight, wherein precise and effective rules influence the trajectory and security of innovation. In the realm of medical

devices, prioritizing patient safety is paramount, especially when regulatory frameworks undergo continual evolution. A significant concern is sometimes termed "innovation's blind spot"—the repercussions of inadequate testing in novel and more visible medical devices. Open and transparent innovation methods, increasingly prevalent in several industries including the medical device industry, promote the incorporation of external ideas and technology, therefore expediting development and market introduction. According to Peter et al., open innovation frameworks enhance value by integrating multiple contributions into organizational processes (Peter et al., 2018). Nonetheless, these swift improvements exacerbate the demand for medical equipment, imposing pressure to expedite product delivery while upholding stringent safety requirements. All organizational units must collaborate to optimize procedures, promote information exchange, and foster a culture conducive to innovation and safety. The implementation of new standards designed to enhance patient security poses considerable hurdles, including heightened demands for monitoring, testing, and documentation. High-risk devices, especially those classified as Class III, can entail significant lifetime expenses owing to the necessity for recurrent clinical testing, which is the most costly aspect of device validation. These requirements may impose financial and operational strains, particularly on small and medium firms, occasionally compelling them to reengineer equipment to conform to reduced risk classifications. Regulating emerging medical technologies is intricate, since the advancement of a technology complicates the evaluation of its safety, usability, long-term efficacy, and total patient benefit. Collaboration between regulatory bodies and medical device developers is essential to reconcile innovation with patient safety, yet the approval process for unique technology is considerably more arduous than for conventional devices.

The Hidden Gap: How Under-reporting Undermines Device Safety

Global apprehension is increasing over the quality of pharmaceuticals, diagnostics, medical devices, and novel healthcare technology. A deterioration in the quality of medical equipment may result in severe repercussions, such as fatalities, extended hospital stays, birth defects, and enduring impairments. The quality and safety of medical devices rely significantly on the constant documentation of adverse occurrences. Nonetheless, underreporting persists as a key concern globally, substantially undermining post-market monitoring programs. Despite regulatory agencies establishing rules and norms for adverse event reporting, numerous manufacturers inadequately invest in this domain, leading to incomplete or substandard submissions to regulators. This immediately undermines both device quality control and patient safety (Kumar et al., 2019). Moreover, when manufacturers submit medical device reports, the terminology employed is sometimes ambiguous, erroneous, or misclassified, complicating the ability of regulatory authorities to evaluate and respond to the material. In several cases, firms inadequately disclose if injuries or fatalities have transpired; even in situations of a deadly occurrence, it is sometimes reported just as a gadget malfunction. Such techniques obfuscate the genuine clinical outcomes of accidents and impede regulators from obtaining a comprehensive and precise understanding of device performance, eventually obstructing effective safety measures and policy formulation.

Breaking the Silence: Challenges in Reporting Device Events

The underreporting of adverse events associated to medical devices continues to hinder effective materiovigilance, with several underlying causes contributing to this ongoing issue. Primary factors encompass user unawareness, insufficient quantities of adverse drug reaction or adverse event monitoring centers, and inadequate funds for reporting from manufacturers (Sharma & Rao, 2018). A significant

number of patients and users lack awareness of the nature of adverse event reporting and the functionality of the reporting system, resulting in the neglect or dismissal of unfavorable device experiences. This deficiency in comprehension also encompasses healthcare workers, especially in nations with inadequate or poorly regulated reporting systems (Kumar et al., 2017). The lack of accessible reporting centers in several areas further deters participation. While proactive and effective monitoring is crucial for safeguarding the safety and quality of medical devices, underreporting considerably undermines post-marketing surveillance and overall patient protection. A primary objective of the Materiovigilance Programme of India (MvPI) is to inform stakeholders about the significance of reporting Medical Device Adverse Events (MDAEs); however, in contrast to the extensive KAP studies in pharmacovigilance, there are significantly fewer investigations into the knowledge, attitudes, and practices pertaining to materiovigilance. Tudy and Meher BR et al. indicated that seniority did not substantially affect knowledge of materiovigilance, presumably due to the concept's novelty and insufficient incorporation into medical curriculum (Tudy & Meher, 2019). The rigorous schedules of healthcare workers contribute to lapses in reporting. In contrast, Gagliardi et al. discovered that many medical professionals deem the reporting of device-related adverse events superfluous or outside their purview, underscoring substantial attitudinal obstacles that exacerbate underreporting (Gagliardi et al., 2016).

Conclusions:

In recent years, medical experts globally have observed a substantial increase in the utilization of medical devices. National-level materiovigilance programs exemplify significant initiatives aimed at safeguarding the safety and efficacy of these devices, fulfilling both patient protection and public health requirements. Robust regulation is crucial to ensure that medical devices are safe, dependable, and able to provide the promised performance prior to market introduction and enhancing public health. As gadgets become safer and more effective, public trust and confidence inherently rise. Medical devices are categorized based on their risk level, necessitating the use of suitable reporting and regulatory frameworks. Currently, adverse event reporting forms for medical devices are predominantly available in English throughout several countries; however, providing these forms in other regional languages would markedly improve patient engagement in reporting, particularly in linguistically varied nations such as India. In the future, value creation will assume a progressively significant position in the global medical device industry. By 2030, medical gadgets are anticipated to significantly enhance health outcomes through direct interaction with users and patients. This transition will probably broaden the emphasis from treatment and therapy to prevention, bolstered by advanced technology, intelligent services, and solutions aimed at achieving superior health outcomes.

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