Review Article

Materiovigilance in Emerging and Established Markets: A Study of USA, INDIA and GCC

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ABSTRACT

Materiovigilance, or the systematic monitoring of adverse events associated with medical devices, is becoming increasingly important in assuring patient safety and healthcare system resilience. This study compares materiovigilance regimes in the US, India, and the Gulf Cooperation Council (GCC) region. The goal is to look at how post-market monitoring systems work across different regulatory landscapes and identify strengths, difficulties, and areas for development. This study uses a qualitative, region-by-region methodology to assess the structure, reporting processes, stakeholder participation, and technology advancements of each country's vigilance system. The United States, with its FDA-led framework, exhibits a mature and organized system that prioritizes obligatory adverse event reporting and rapid treatments. India has made considerable policy achievements through the Materiovigilance Programme of India (MvPI), but it still faces infrastructure and cultural hurdles. Saudi Arabia leads the GCC in terms of strong mechanisms, including the National Centre for Medical Device Reporting (NCMDR) and Saudi Vigilance. Bahrain and the UAE are showing signs of regulatory maturity, whilst Qatar and others are still in the early phases of implementation. The findings demonstrate that materiovigilance is more than just a compliance requirement; it is also a vital driver of healthcare safety and innovation. The research calls for more regional coordination, the use of digital reporting mechanisms, and capacity building, particularly in emerging economies, in order to align with international best practices and reduce device-related hazards internationally.

Keywords: Materiovigilance, Medical devices, Post-market surveillance, Regulatory frameworks, Emerging markets, Patient safety.

INTRODUCTION

The word 'Medical device' refers to any equipment, apparatus, implant, in vitro reagent, or software used to diagnose or treat diseases in people. Medical devices differ in both intended purpose and indications for usage. Medical devices that are frequently used in clinical practice include cardiac stents, glucometers, internal prosthetic replacements, automated external defibrillators (ADE), orthopaedic implants, disposable hypodermic needles and syringes, and so on. The global prevalence of metabolic diseases such as stroke, obesity, diabetes, and cancer is expected to drive up demand for these devices. As a result, it is critical to ensure their efficacy and quality. However, device quality varies, and even the greatest technology may malfunction in a clinical context. Furthermore, these technologies may cause safety issues that inadvertently harm the patients. As a result, post-marketing monitoring is critical in fixing these concerns because it assists in measuring the performance of devices and focuses on their safety.

Materiovigilance refers to the close monitoring of any unfavourable occurrence caused by a medical device, which includes collecting, reporting, and estimating unwanted events. It also covers regulatory agency responses to the occurrence, as well as guaranteeing safety and remedial steps throughout the post-marketing period. The fundamental purpose of materiovigilance is to increase the guarantee of health safety for patients, users, and others by reducing the occurrence of an incident. Globally, regulatory agencies are beginning to understand the importance of materiovigilance. For example, the United States Food and Drug Administration (FDA) have a well-established Medical Device Reporting (MDR) system, whereas India began the Materiovigilance Programme of India (MvPI) in 2015 to improve device safety. Similarly, nations in the Gulf Cooperation Council (GCC), such as Saudi Arabia, are building national frameworks that are in line with global norms to strengthen medical device vigilance. These tools are supplemented with real-world case studies that show how prompt incident reporting and analysis have prevented future harm and influenced regulatory improvements.

In 1992, the Global Harmonization Task Force (GHTF) was formed, bringing together five nations: the United States, Canada, Japan, Europe, and Australia. The major goal of this alliance was to promote consistency in the regulatory frameworks governing medical devices at the national level, with a shared emphasis on guaranteeing efficacy and safety. The IMDRF was established in 2011 to monitor adverse incidents using medical equipment. It was created to speed up the convergence and harmonization of medical device regulations across borders[1-2].

A global inquiry discovered that some medical devices were still being offered in global marketplaces even after they were deemed dangerous. Such dangerous medical devices have resulted in over 1.7 million documented injuries globally, as well as over 83,000 fatalities. Breast implants, pacemakers, contraceptives, incubators, and prosthetic hips grafted into patients' bodies are among the most common and risky medical devices that have resulted in disastrous results [3].

For example, in the US, the Essure contraceptive implant was connected to over 27,000 adverse event reports, including severe pelvic discomfort and device migration, eventually leading to its market discontinuation in 2018 under FDA limitations [4]. In India, the Johnson & Johnson ASR hip implant crisis exposed severe regulatory failings when hundreds of patients suffered from implant failures and metal toxicity, forcing a government investigation and compensation scheme in 2018 [5]. Similarly, in the GCC area notably in Saudi Arabia, the Saudi Food and Drug Authority (SFDA) issued repeated safety alerts following reports of faulty cardiac devices such as pacemakers and defibrillators, prompting a review of their medical device surveillance procedures. These case studies from several nations demonstrate how gaps in post-market monitoring and delayed regulatory action can cause substantial patient damage, emphasizing the critical need for strong, globally coordinated materiovigilance systems [6].

METHODS

Materiovigilance in the United States:

Medical devices in the United States are regulated by the United States Food and Drug Administration, also known as the FDA. A device can lawfully be placed on the market if the FDA has cleared it and decided that it is safe and acceptable for its intended application [2]. The FDA categorizes medical devices into three categories: Class I, Class II, and Class III, based on the amount of control required for safety and efficacy, as well as marketing regulations. The Medical Devices Regulations (21 CFR Part 803) specify the requirements for reporting adverse occurrences in marketed medical devices [7].

Regulatory Acceptance Pathways for Medical Devices in the USA

In USA, 3 regulatory pathways are being used for device approval

1. The pre-marketing notification (PMN),
2. Pre-market approval (PMA), and
3. Humanitarian device exemption (HDE).

Reporting of adverse events in medical devices

The Federal Food, Drug, and Cosmetic Act, under the Section 519, grants permission to the FDA to require medical device reports from manufacturers, device user facilities, and importers. In addition, they are obliged to report to the FDA certain adverse outcomes that occur as a result of medical devices.

Mandatory reporting requirements for medical devices

The 21 CFR Part 803, reporting of medical device consists of some mandatory requirements for importers, manufacturers, device users' amenities to report certain product problems including device linked adverse outcomes to the FDA.

Manufacturers

When they learn that one of their products has caused death or serious injury, they tell the FDA. They must also alert authorities if they determine that the device has malfunctioned and is causing or contributing to serious harm or death.

Importers

If they see one of the devices has caused death or serious harm, they notify it to the manufacturer or the FDA. Importers, on the other hand must only report malfunction devices to the manufacturers.

Device user facilities

Hospitals, nursing homes, outpatient diagnostic facilities, and surgical institutions, to name a few, fall within this group. These consumer facilities should be designed to notify adverse incidents with medical devices to the producer or the FDA [3].

Reporting timeline

30 calendar days for death, serious harm, and malfunction. Manufacturers report occurrences that require remedial action within five working days. Importers have 30 calendar days to report deaths, serious injuries, and malfunctions. 10 working days - By January 1 of the prior year, user facilities must report device-related deaths and serious injuries, as well as an annual summary of deaths and serious injuries.

The FDA requires importers, manufacturers, and device user facilities to report device-related adverse events to the FDA using Form FDA 3500A, while healthcare professionals, patients, caregivers, and consumers must report them voluntarily using Form FDA 3500 [8].

Adverse Event Reporting Tools

MAUDE Database

A publicly available repository including adverse event reports submitted by mandatory reporters (manufacturers, importers, device-user institutions) as well as volunteer reporters (healthcare professionals, patients, and consumers) [9].

MedWatch & eMDR Portal

MedWatch is the FDA's safety and adverse event reporting program. Healthcare professionals, consumers, and patients can file voluntary reports using Form FDA-3500, while obligatory reporters utilize Form FDA-3500A.

eMDR (Electronic Medical Device Reporting): An electronic system allowing mandatory reporting by manufacturers, importers, and user facilities [10].

Materiovigilance in India:

The D&C Acts of 1940 and Rules of 1945 control the performance, quality, and safety of medical devices in India. For a long time, India lacked a suitable technique for tracking the negative effects associated with the use of medical devices. In 2017, the Indian government

collaborated with the Drugs Technical Advisory Board to create the Medical Device Rules. These regulations are intended to regulate the import, manufacturing, and sales of medical equipment and devices, as well as to ensure a suitable distribution chain throughout the country[2].

Materiovigilance programme of India

The Materiovigilance Programme of India (MvPI) was launched on July 6, 2015, at the Indian Pharmacopoeial Commission (IPC) in Ghaziabad by Drug Controller General of India DCG(I). The program's main goal is to raise awareness among health care providers about the importance of medical device adverse events (MDAE). It also focuses on a device's benefit-risk profile, monitors MDAE, and communicate these findings to all key parties. IPC is the National Coordination Centre (NCC) for MvPI, and its role is to monitor adverse occurrences of medical devices observed in the Indian public. SCTIMST serves as the National Collaborating Centre.

MvPI is regulated by the Central Drug Standard Control Organization (CDSCO), and the National Health System Resource Center (NHSRC) provides technical assistance. To verify the completeness of a case, examine MDAE data, and submit reports to NCC, 26 Medical Device Monitoring Centers (MDMCs) and Adverse Drug Reaction Monitoring Centers (AMCs) have been established [8].

The MvPI aims to

1. Establish a national strategy for assessing patient safety,
2. Examine the benefit-risk ratio of medical devices,
3. Generate evidence-based information for equipment linked to unfavourable incidents,
4. Share safety-related information with industry stakeholders, and collaborate with international and healthcare organizations to exchange data [2].

Adverse Event Reporting:

MDAE are reported using the adverse event reporting system. It is a significant tool for improving the well-being of patients and medical device users by lowering the frequency of adverse events. Recorded occurrences are reviewed, and information is distributed to prevent or lessen the consequences of such repeats [8].

Reporting System of the Medical Device Associated Adverse Events

Who can report MDAEs?

Healthcare personnel and patients can report MDAEs to SCTIMST or NCC. Additionally, CDSCO-recognized medical device makers or importer traders can report AEs unique to their device directly to SCTIMST or NCC in Thiruvananthapuram, Kerala, India.

What to Report?

MDAEs of all sorts (known or unknown, serious or non-serious, infrequent or regular) can be recorded, independent of the recognized causal link. Details of an AE include an event narrative, a medical device description, and any related risk to the patient/user from past usage, which may be noted in the MDAEs reporting form.

How and Whom to Report MDAEs?

MDAEs can be reported to MAMCs using the MDAE reporting form, which is available on IPC's official website (www.ipc.gov.in). Research colleagues from MDMCs then email this completed form to NCC at mvpi@sctimst.ac.in. Alternatively, the NCC PvPI toll-free helpline 1800-180-3024 can be utilized to report MDAEs. All reported cases at NCC are eventually examined, analysed, and transmitted to the WHO-Uppsala Monitoring Centre (WHO-UMC)[1].

Reporting timeline

Death or serious public threat reported by manufacturer within 5 working days, MDAE reporting form, causality assessment report, corrective, preventive action within 30 calendar days by manufacturer and health care professional[8].

Materiovigilance in the GCC Region:

The Gulf Cooperation Council (GCC) is a regional, intergovernmental, political, and economic union established on May 25, 1981. It comprises six Middle Eastern countries: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates.

The regulatory framework for medical devices in GCC countries is controlled by each country's national health authorities, who are in charge of establishing and implementing legislation and procedures for medical device registration and market access**.**

Regulatory framework

In addition to funding health care, each country's health ministries are ultimately in charge of regulatory monitoring. In terms of the GCC's medical device regulatory environment, each member state has its own system that is at different stages of maturity [11].

Medical device vigilance systems are overseen by the respective national regulatory authorities given in Table 1.

Table 1: Respective national regulatory authorities

Country	Regulatory Authority
Baharin	National Health Regulatory Authority
Kuwait	Ministry of Health
Oman	Ministry of Health
Qatar	Ministry of public Health
Saudi Arabia	Saudi Food and Drug Administration
UAE	Ministry of Health and prevention

1. Materiovigilance in Saudi Arabia:

The Saudi Food and Drug Authority (SFDA) regulates medical devices in accordance with the Saudi Medical Device Interim Regulation (2021), which takes effect in March 2021, and the Medical Device Law (Article 23) [12].

Reporting medical device incidents, complaints, and adverse events is the essential post-marketing surveillance activity companies and their authorized representative (AR) must comply with in Saudi Arabia.

Who Should Report?

Manufacturers, authorized representatives, importers, distributors, and healthcare providers.

Where to Report?

Adverse event reports and related documents can be reported to SFDA through one of the following channels:

National Centre for Medical Device Reporting (NCMDR)

Saudi Vigilance.

Required Documents Occurred Inside Saudi Arabia

Initial Report

An initial report is the first piece of information reported concerning an undesirable incident. Reporters must include investigation reports, technical documentation, and test results linked to the medical device connected with the adverse event, depending on the stage of the investigation and the availability of information. The initial report must include the information specified on the SFDA medical device reporting form.

Follow-up Report

A report that provides supplementary information about adverse events that was not previously available, such as additional information, investigation progress, and actions taken.

Final Report

The latest adverse event report submitted must include all information, specifics, measures done, and final recommendations. It must also mention the CAPA used by the manufacturer or an authorised representative for the SFDA evaluation.

Reporting Timeframe

Manufacturers or its AR must report an incidence or adverse occurrence to the SFDA within the timeframe specified below:

No later than two calendar days-

If the occurrence or adverse event poses a serious public health risk.

Immediately, not later than ten calendar days-

For an occurrence or bad event that causes unintended death or significant harm.

All such incidences and adverse events should be reported within 30 calendar days [13].

2. UAE:

Medical device vigilance in the UAE is administered by the Ministry of Health and Prevention (MOHAP) in accordance with Federal Law No. 4 (2015) and the Medical Device Guidelines 2018 [12]. This entails post-market surveillance, such as adverse event reporting and prompt notification of recalls and remedial measures. Manufacturers are obligated to report adverse occurrences within ten days [14].

Reporting Requirements

The report of the adverse event should contain as much detail as possible, and should not be delayed for any reason. Below table 2 summarize Reporting Requirements with the time frame.

3. BAHARIN

In Baharin National Health Regulatory Authority governs medical devices.

Adverse events Reporting

Anyone can report an adverse event associated with a medical device to NHRA. Patients, users, healthcare professionals and suppliers are all encouraged to report an adverse event that has occurred and there is a concern about the safety of the device or its use [15]. Reporting timeframe as shown in table 3.

4. OMAN

The Oman Ministry of Health oversees medical devices under the Medical Device Regulations (2019) implemented in January 2019.

Medical Device Event Reporting Framework

Reportable Events

Events resulting from equipment failure, degradation, labelling difficulties, or user mistakes must be reported. These include patient harm, misdiagnosis, therapy discontinuation, and health decline. User mistakes caused by bad design, insufficient training, or wrong use are also deemed reportable.

Non-Reportable Events

Events not requiring reporting include: device deficiencies detected before use with no harm, events caused solely by patient condition, failure due to expiry or shelf life, events mitigated by fail-safe mechanisms, those under existing recall alerts, and predictable events mentioned in the IFU (Instructions for Use).

Roles of Reporters

Healthcare practitioners and users must report adverse events, particularly if the maker is unknown. Accurate documentation and fast action to protect the patient, personnel, and equipment are required.

Table 2: Reporting Requirements with time frame

	WHAT TO REPORT	WHEN	TO WHOM	REPORT FORM
Healthcare Providers/ Professionals	1.Deaths, serious injuries and malfunctions	1.Within 24 hours of becoming aware of an event	DOH Pharmacovigilance & Drug Education at PVE@doh.gov.ae & manufacturer/ distributors	Online PDF Form
	2. Event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	2. No later than 5 days after the day that you become aware of a reportable event		
	3. Other medical device reports with no urgent safety impact e.g. Incident Report, use errors, product quality issues, and therapeutic failures or any device product problems	3. Expedited reporting is required but in no case later than 15 days.	DOH Pharmacovigilance & Drug Education at PVE@doh.gov.ae & manufacturer/ distributors	
Manufacturers, marketing authorization holder, importers, authorized agents/ representatives, distributors, suppliers and registrants or any other person who is responsible for placing the device on the market	1.Deaths, serious injuries and malfunctions 2. Event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	1 & 2: Within 5 days of becoming aware of an event	DOH Pharmacovigilance & Drug Education PVE@doh.gov.ae	Online PDF Form
	3.Other Medical device reports with no urgent safety impact e.g. Incident Report, use errors, product quality issues, and therapeutic failures or any device product problems	3. Expedited reporting is required but in no case later than 15 days.		

Table 3: Reporting Time Frame

Reporter	Type of problem	Report to whom	Time frame
Manufacturer	Death / Serious injury	NHRA	10 working days.
	Other Problems not associated with high risk or injury.	NHRA	30 working days.
AR / Supplier	Death / Serious injury	Manufacturer / NHRA	10 working days.
	Other Problems not associated with high risk or injury	Manufacturer / NHRA	30 working days.
Healthcare Facilities	Death / Serious injury	Supplier / Manufacturer / NHRA	10 working days.
	Other Problems not associated with high risk or injury.	Supplier / Manufacturer / NHR*/A	30 working days.

Role of Local Agents

Local agents must report serious events to both the Medical Device Control Department and the manufacturer. They must coordinate investigations, record outcomes, and ensure compliance with reporting practices.

Role of Manufacturers

Manufacturers must report serious events, conduct timely investigations, inform users of risks, and coordinate recalls or corrective actions with local agents when necessary.

How to Report

Fill the form (Medical Device Adverse Event Reporting Form) provided by the Medical Device Vigilance Section, Ministry of Health, Oman, and email it to: vigilance-md@moh.gov.om

Reporting Time Frame

Within 2 working days for major public health hazards. Within 10 working days for sudden death/serious injury. Within 30 working days for low-risk incidents [16].

5. QATAR

In 2017, Qatar introduced Medical Device Regulations, which are governed by the Qatar Council for Healthcare Practitioners (QCHP) or the Ministry of Economy and Commerce (MEC)for device registration.

The National Health Strategy project update acknowledges that "Qatar does not currently have an effective system to regulate the introduction and continued use of medical devices within the State." Despite Qatar having the least established regulatory structure among the GCC's three main economies, there are some broad standards for medical device registration [11].

6. KUWAIT

The Kuwait Ministry of Health oversees medical devices under the Medical Device Law (2018), which went into effect in January 2018.

While the Ministry of Health technically recognises post-market surveillance (PMS) duties such as periodic safety assessments, the government still lacks a dedicated materiovigilance program and an adverse event reporting system for the general public. According to studies, healthcare workers continue to be unaware of adverse event reporting systems, and there is no evidence of an organised or operational monitoring infrastructure [17].

RESULTS

"To demonstrate the real-world implications of materiovigilance in medical devices, two case studies were analysed. The first examines a failure in electronic durability (Medtronic MiniMed insulin pumps, U.S.), while the second reveals systemic surveillance and regulatory delays (Johnson & Johnson's ASR hip implants, India). These cases highlight both technical and institutional resilience challenges in different regulatory environments."

Case Study 1: Medtronic MiniMed 600 and 700 Series Insulin Pump Battery Recall (United States)

Medtronic initiated a Class I recall of MiniMed 600 and 700 series insulin pumps in October 2024 after allegations surfaced that even a single drop might harm internal circuitry, resulting in drastically shorter battery life, early insulin supply cutoff, and health hazards such as hyperglycemia and DKA. From January 2023 to September 2024, the company received 170 reports of hyperglycemia and 11 reports of DKA possibly related to this condition.

Cause of the Problem:

Internal electrical components are harmed by physical impact (drop or bump), which causes false battery alarms and early pump shutdown.

Corrective Actions:

According to FDA guidelines, Medtronic recommended carrying extra batteries, calling support for early battery depletion, replacing batteries as soon as the "Low Battery Pump" signal occurs, and providing new pumps as necessary[18].

Case Study 2: J&J ASR Hip Implant Recall and Regulatory Delays (India)

The DePuy ASR hip implant, used in around 4,700 surgeries in India, was globally recalled in 2010 due to high failure rates and adverse health outcomes. India's response lagged significantly behind other countries, patients continued receiving implants post-global recall, exacerbating patient harm.

Cause of the Problem:

A design fault that caused metal wear and metallosis was exacerbated by insufficient surveillance, voluntary reporting, regulatory loopholes, delayed recall enforcement, and a lack of patient tracking.

Corrective Actions:

Eventually, the implants were recalled, but by then, the harm had already been done. Investigations resulted in the cancellation of import permits, the establishment of compensation plans, and changes to India's materiovigilance and medical device regulation frameworks[19].

DISCUSSION

Critical issues in materiovigilance that impact the efficacy and safety of medical devices are brought to light by the case studies from the United States and India. The mechanical impact that causes electronic resilience failure in the United States emphasizes how crucial material durability is when designing devices. According to this failure domain, devices need to be put through a thorough resilience testing process in order to endure the physical stressors that come with regular use. On the other hand, design faults combined with delayed recall procedures highlight serious regulatory supervision deficiencies in the Indian situation, which highlights systemic difficulties. Regulatory delays can increase patient safety concerns by extending exposure to defective devices, as these findings are consistent with other publications.

Collectively, these incidents show that materiovigilance is about more than just technical device quality; it's also about the strength of the regulatory environment. To prevent such failures, design standards and post-market surveillance measures must be strengthened. Future initiatives should focus on integrating materiovigilance procedures across areas and improving real-time monitoring to allow for quick

remedial measures. Addressing these issues is crucial to ensuring patient safety and preserving trust in medical technologies.

CONCLUSION

Materiovigilance is growing as a critical component of worldwide patient safety, particularly as medical device use grows. This analysis demonstrates that, while the United States has a model vigilance system, India and the GCC nations are at varying degrees of development. The United States system, overseen by the FDA, is technologically advanced, transparent, and heavily regulated. India has made tremendous regulatory progress through the Materiovigilance Programme of India (MvPI), but obstacles remain in areas such as underreporting, awareness, and infrastructure. Saudi Arabia leads the GCC countries in formal post-market monitoring procedures, with the UAE, Bahrain, and Oman establishing frameworks. Qatar and Kuwait are still in the early phases of implementation, needing strong infrastructure and involvement. The report highlights the necessity of integrated digital platforms, stakeholder training, regional cooperation, and conformity to international standards like those from the IMDRF and WHO in order to close these operational and regulatory gaps. Ultimately, enhancing materiovigilance is a public health necessity as well as a regulatory necessity to reduce device-related dangers and advance safer, more efficient healthcare systems throughout the world.

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