A Comparative Analysis of Pharmacists' and Healthcare Professionals' Knowledge, Attitudes, and Practices in Materiovigilance: A New Field for Investigation in Pharmaceutical Education

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ABSTRACT: Materiovigilance is a critical component of healthcare that focuses on ensuring the safety, quality, and performance of medical devices and materials used in patient care. The term “Materiovigilance” is derived from the Latin words “mater,” meaning material, and “vigilare,” meaning to watch or monitor[1]. As the use of medical devices and materials continues to grow and evolve, the importance of Materiovigilance has become increasingly evident. Medical devices can range from simple supplies like gloves and syringes to complex equipment like pacemakers and ventilators. Ensuring the safety and effectiveness of these devices is crucial for preventing adverse events, reducing healthcare costs, and improving patient outcomes[1].

Materiovigilance involves a multidisciplinary approach that incorporates principles from materials science, biomedical engineering, clinical practice, and regulatory affairs. It requires collaboration among healthcare professionals, manufacturers, regulators, and patients to identify and mitigate risks associated with medical devices and materials[2]. By prioritizing Materiovigilance, healthcare systems can minimize the risk of device-related adverse events, optimize device performance, and ultimately improve the quality of patient care[2]

Keywords- Materiovigilance, healthcare, medical devices, monitor, safety, patient care, optimize device performance, minimize risk

Medical Device Safety

1. Device-Related Adverse Events: Identifying, reporting, and investigating adverse events related to medical devices.

2. Risk Management: Identifying, assessing, and mitigating risks associated with medical devices[3]

Material Selection and Testing

1.Biocompatibility Testing: Evaluating the compatibility of medical device materials with the human body.

2. Material Selection: Choosing materials for medical devices that are safe, effective, and durable.

3.Material Characterization: Understanding the properties and behaviour of medical device materials[3].

Regulatory Compliance

1. Regulatory Frameworks: Understanding regulatory requirements for medical devices, such as FDA 21 CFR Part 820 and ISO 13485.

2.Device Registration and Approval: Registering and obtaining approval for medical devices from regulatory authorities[3].

Post-Market Surveillance

1. Device Monitoring: Continuously monitoring medical devices for safety and performance issues.

2. Adverse Event Reporting: Collecting and reporting adverse event data related to medical devices.

3. Device Recalls: Managing device recalls and field corrections[3].

Human Factors Engineering

1.User-Centered Design: Designing medical devices with user needs and safety in mind.

2. Device Usability: Ensuring medical devices are easy to use and minimize user error.

3.Human-Device Interface: Optimizing the interface between medical devices and users[3].

MEDICAL DEVICE SAFETY IN ADVANCING MATERIOVIGILANCE

MEDICAL DEVICE SAFETY:

Medical device safety is one of the critical aspects of healthcare as it ensures the safety and effectiveness of medical device via diagnose, treat and prevent diseases in fig 1[4].

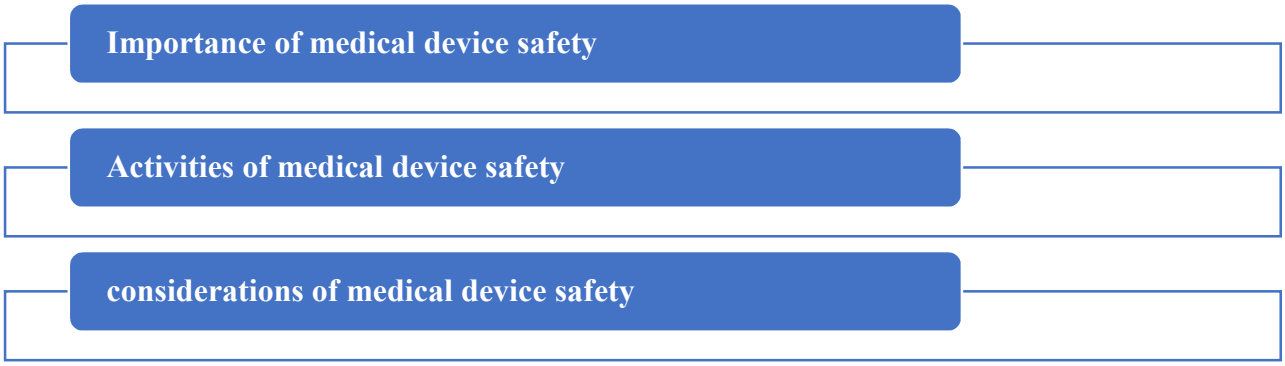

Fig 1: Critical aspects of healthcare

IMPORTANCE OF MEDICAL DEVICE SAFETY:

1. PATIENT SAFETY:

Medical device can pose risk to patients if they are not designed, manufactured or used correctly.

2. ADVERSE EFFECT OF THE DEVICE:

The adverse effect of the medical device can be harmful to patients including any injury or it may even cause death.

3. REGULATORY COMPLIANCE:

Manufacturers of the medical devices comply with regulatory requirements which is related to design, test and labelling of the device[4].

ACTIVITIES OF MEDICAL DEVICE SAFETY:

1. ADVERSE EFFECT REPORTING:

The healthcare professionals and manufacturers must report to the adverse effect which is related to regulatory authorities.

2. DEVICE SURVEILLANCE:

The regulatory authorities and manufacturers should monitor the medical devices for the safety concerns and failures of the device.

3. CORRECTIVE ACTIONS:

The regulatory authorities and the manufacturers should take the strict and corrective actions to address the safety concerns[4].

CONSIDERATIONS OF MEDICAL DEVICE SAFETY:

1. DESIGNING OF THE DEVICE:

The medical devices must be designed properly with much safety in mind because as it can contain user error and produce failure of the device.

2. MANUFACTURING QUALITY:

In manufacturing quality, all the medical devices must be manufactured with high quality materials so this ensures the safely and effectively.

3. TRAINING OF THE USER:

The healthcare professionals must be properly trained to use the devices safely and effectively.

4. MAINTENANCE AND REPAIR:

Medical devices should be maintained and repaired properly to ensure the function safely[4].

REGULATORY FRAMEWORK;

1. FDA (US):

The US food and drug administration regulates the medical devices in the United States.

2. EU MDR (Europe):

The European Union’s medical device regulation (MDR) regulates the medical devices in Europe.

3. ISO 13485 (International):

The International Organization for Standardization (ISO) 13485 standard provides a framework for medical device quality management systems[4.]

THE ROLE OF HUMAN FACTORS ENGINEERING (HFE) IN ADVANCING MATERIOVIGILANCE

HFE is a collective study of all human sciences, to enhance the match between people and the world via the design of products, processes, etc. It is based on the human safety, satisfaction, performance with systems and medical devices.[4]

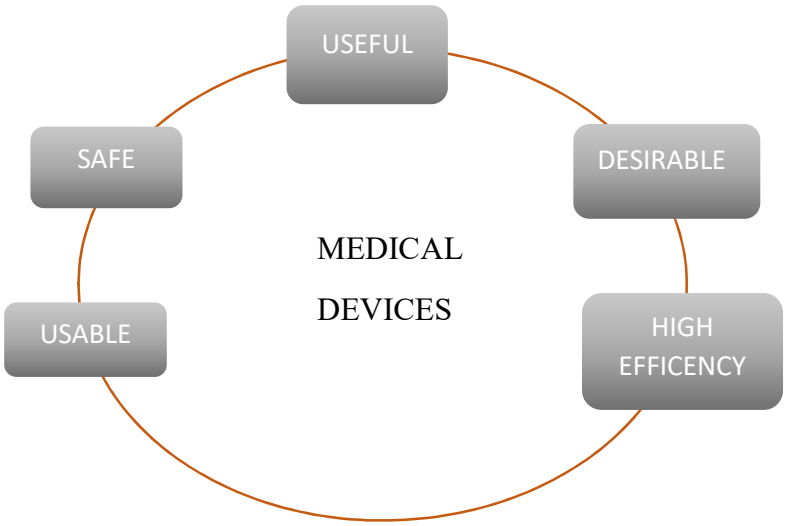

Fig 2: Critical aspects of healthcare

Artificial Intelligence, virtual simulators, digital twins - the collective studies of these things play an important role in the development and enhancement of medical devices.[4]

In Implants, HFE plays a vital role by designing a ROTATORY BLOOD PUMP which exactly mimics the original heart which is called as BiVACOR artificial heart -----Case Study Incorporation of main schemes of HFE in the user-centered design. Helps in reduction of errors and enhances its efficiency. It improves the Human-system interactions and modernized tools likes eye-tracking Systems could upgrade the potent results of the entire system.[4]

HFE/Ergonomics mainly depends on human centered device because the design proceeds with human /user needs and requirements for their and other healthcare professional safety. HFE ensures that medical devices are safe to use since they have many developing and evaluation factors which is clearly resolves most of the risk factors.[4]

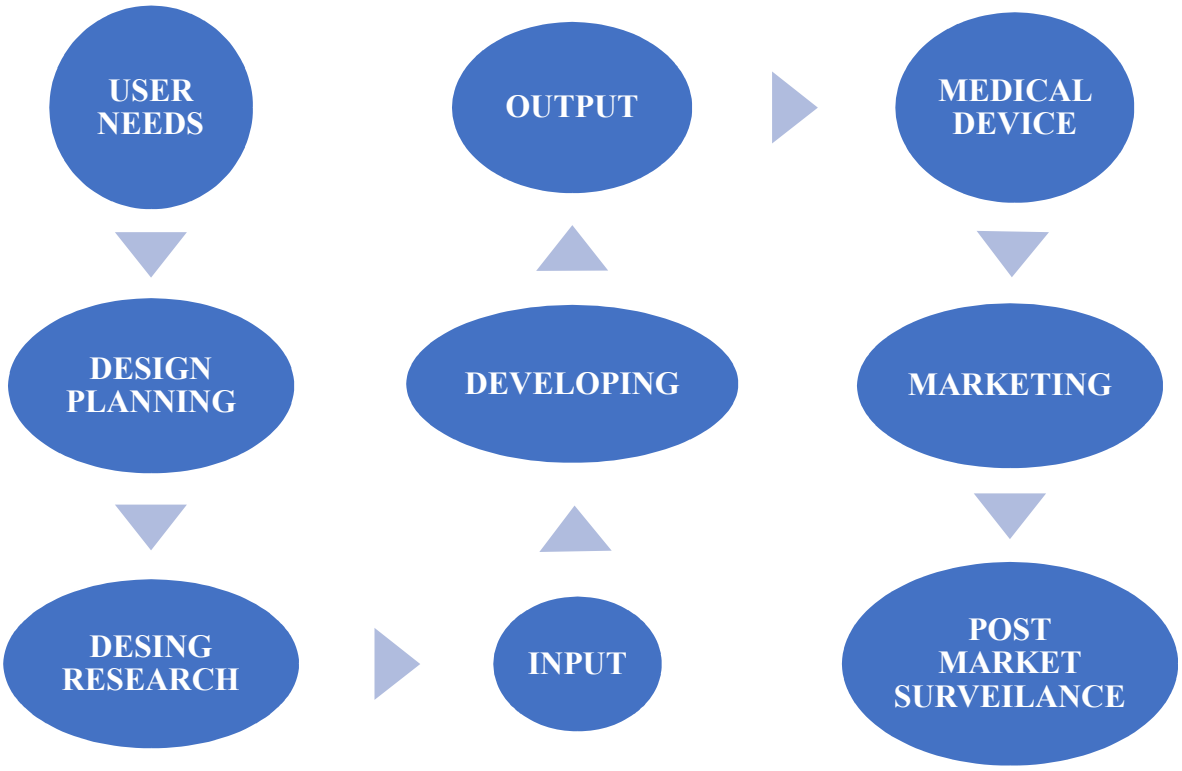

Fig 3: Critical aspects of healthcare

MATERIAL SELECTION AND TESTING

MATERIAL SELECTION: Material selection is the selection of materials for certain specific application of a medical device. Mainly the selection is based on biocompatibility, durability, efficiency of final product. Materials are mainly selected based on patient safety, performance of the designing device.[5]

STEPS:

- Identifying - based on its properties (flexibility, durability)
- screening - screened based on consideration of certain factors such as environmental and regulatory factors.
- analyzing [performance and cost] - analyze the screened materials for performance and cost effective.
- Finalizing – the good material from the above process is finalized.[5]

TESTING:

It is the process of assessment of product to find its compatibility, Safe nature, standards. In this the materials are tested for various factors to meet the regulatory compliance and sustainability.[5]

TYPES:

- Physical testing - It is based on properties such as thermodynamics, optical activity, density.
- Chemical testing - It is based on the properties such as corrosion resistant, chemical stability.
- Biocompatibility testing - materials are in contact with biological system hence the testing is done with the body and MD (testing for irritation, toxicity, interactions with blood)
- Performance testing-testing for performance with simulations (environment, load testing)

Testing of materials could enhance the safety and sustainability of medical devices by determining the risks such as toxicity, mechanical failure, or degradation before and during market use.[5]

COMBINED BENEFITS

Reduction of risks, upgradation of patient safety and increased biocompatibility. Reliability of device could be maintained and decreased device failure. Testing gives the data which is necessary to meet regulatory standards. Cost Efficiency -correct selection and testing prevents expensive products or medical devices RECALL. Selection and Test of material paves the way for innovation and development in older designs on the material.[5]

A good selected and tested materials only cause small amount of post surveillance issues which in turn reduces recall of products.[5]

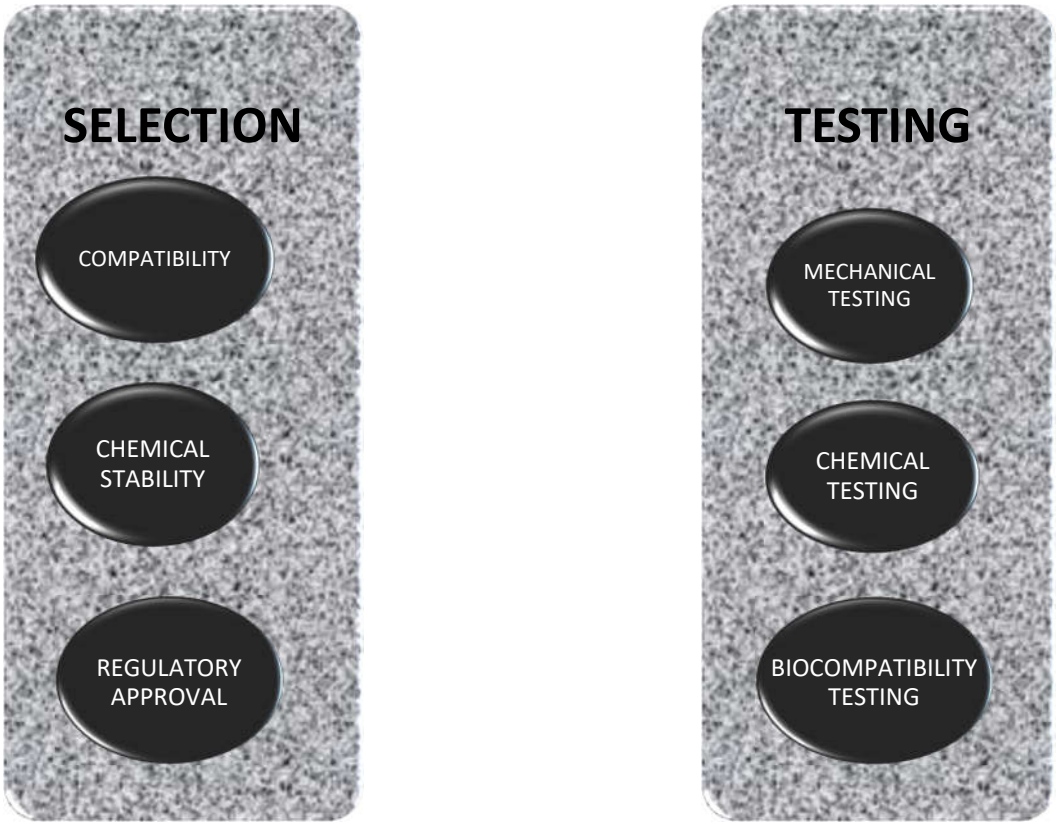

Fig 4: Benefits of materiovigilance

MEDICAL DEVICE USER INTERACTION IN MATERIOVIGILANCE

The process of keeping an eye on and controlling the functionality and safety of medical devices is known as meteriovigilance. Knowing how medical devices and their users interact is a crucial component of materiovigilance. Interactions between patients, medical devices, and healthcare providers are referred to as medical device user interaction.[6]

RECENT ADVANCEMENTS IN MEDICAL TECHNOLOGY

Applications for medical devices have increased dramatically as a result of recent developments in medical technology. These tools diagnose, prevent, and treat a variety of illnesses; they range from basic inhalers to sophisticated surgical instruments. As their use grows, so do safety concerns. Post-marketing data is essential for guaranteeing the performance and safety of devices.[6]

IMPORTANCE OF MEDICAL DEVICE USER INTERACTION

In order to guarantee the safe and efficient use of medical equipment, user contact is crucial. Medical device performance may be impacted by user interactions, and improper usage of the equipment may result in problems. Additionally, user interactions can yield important

information on the functionality and safety of medical devices, which can help guide materiovigilance efforts.[6]

DEVICE RISK CLASS TYPES[6]

Table 1: Devices risk class types

DEVICE RISK CLASS	TYPES OF RISK	EXAMPLES
CLASS A	LOW RISK	BOLSTER SUTURE, ALCOHOL SWAPS, NASOPHARYNGEAL CATHETER
CLASS B	LOW MODERATE	DISINFECTANTS, INTRAVENOUS CATHETER, RECTAL CATHETER
CLASS C	MEDERATE HIGH	BILIARY STENTS, BONE CEMENT, IMAGING CATHETER, CT SCAN, MRI, DEFIBRILLATOR, X-RAY MACHINE, GLUCOMETER, BLOOD BAGS, NON-ABSORBABLE SUTURES, ANAESTHESIA MACHINES ETC.
CLASS D	HIGH	CORONARY STENT, HEART VALVE, COPPER-T

Factors Influencing Medical Device User Interaction

- Device design and usability
- User training and education
- Clinical environment and workflow
- Patient factors, such as age and health status[6]

To improve medical device user interaction, several strategies can be employed, including

- Human-centered design approaches to develop user-friendly devices
- Providing comprehensive user training and education programs
- Conducting usability testing and feedback sessions
- Encouraging reporting of adverse events and near misses related to user interaction[6]

BENEFITS OF MATERIOVIGILANCE

Materiovigilance is a system that identifies, reports, and analyses any adverse events that might be linked alongside the usage of therapeutic devices used in the medical industries. The goal of materiovigilance is to provide protection for patient health by preventing the occurrence of MDAEs (medical devices associated adverse effects) and improving the design and efficiency of medical devices.[7] It is no doubt that with advancement in the field of technology there has been a significant influence on healthcare practices which has further resulted in improvement in healthcare results and outcomes. Few of the high-tech and technological up-gradings include drug, and others.[7]

All of these resulted in a rapid increase in the applications of therapeutic devices or medical devices in healthcare facilities. Materiovigilance or in short Mv, has a similar goal and approach to ensure and provide patient safety as that of pharmacovigilance but the difference is that materiovigilance ideally aims at the monitoring of the adverse effects associated with medical and therapeutic devices.[8]

Which field of medicine is independent of medical devices? Medical devices are commonly used in prevention, diagnosis, and of course the treatment of a wide range of ailments and diseases. These medical devices include very simple aerosol inhalers to complicated operation theatre and surgical devices. Globally, the need for medical devices has risen exponentially. This is due to the increased cases and more common incidence of several chronic diseases, diabetes, cancer, stroke and obesity.[8]

On one side simultaneously as the use of therapeutic devices in the medical field is significantly rising, the considerations with respect to their safety are on the rise as well. There are so many benefits associated with materiovigilance.[9]

- First and fore most it ensures patient safety.

It significantly contributes to public health by identifying the potential safety issues associated with the medical devices more accurately and quickly. Importantly, it promotes patient safety by recognizing the adverse events that could potentially result in patient harm.[9]

- Documenting and reporting adverse events

Any adverse events in regards to the therapeutic devices in the medical field used in India can be reported. This is disregarding of whether they are identified or unidentified, significant or

insignificant, recurring or rare. Accompanying that, any failure to function properly or damage, or even degeneration in characteristics or prosecution of any medical device or lapse, blunders or impreciseness in labelling or instructions for usage can be reported.[9]

This not only increases patient safety but it also encourages Medical Device Manufacturers/ Importers to put products in market with a sense of ethical business, analyse and improve design and performance of products. Communication of the information regarding the security and the safety on the use of therapeutic devices to various stakeholders to minimizes the dangers and risks pertaining to the adverse effects.)[9]

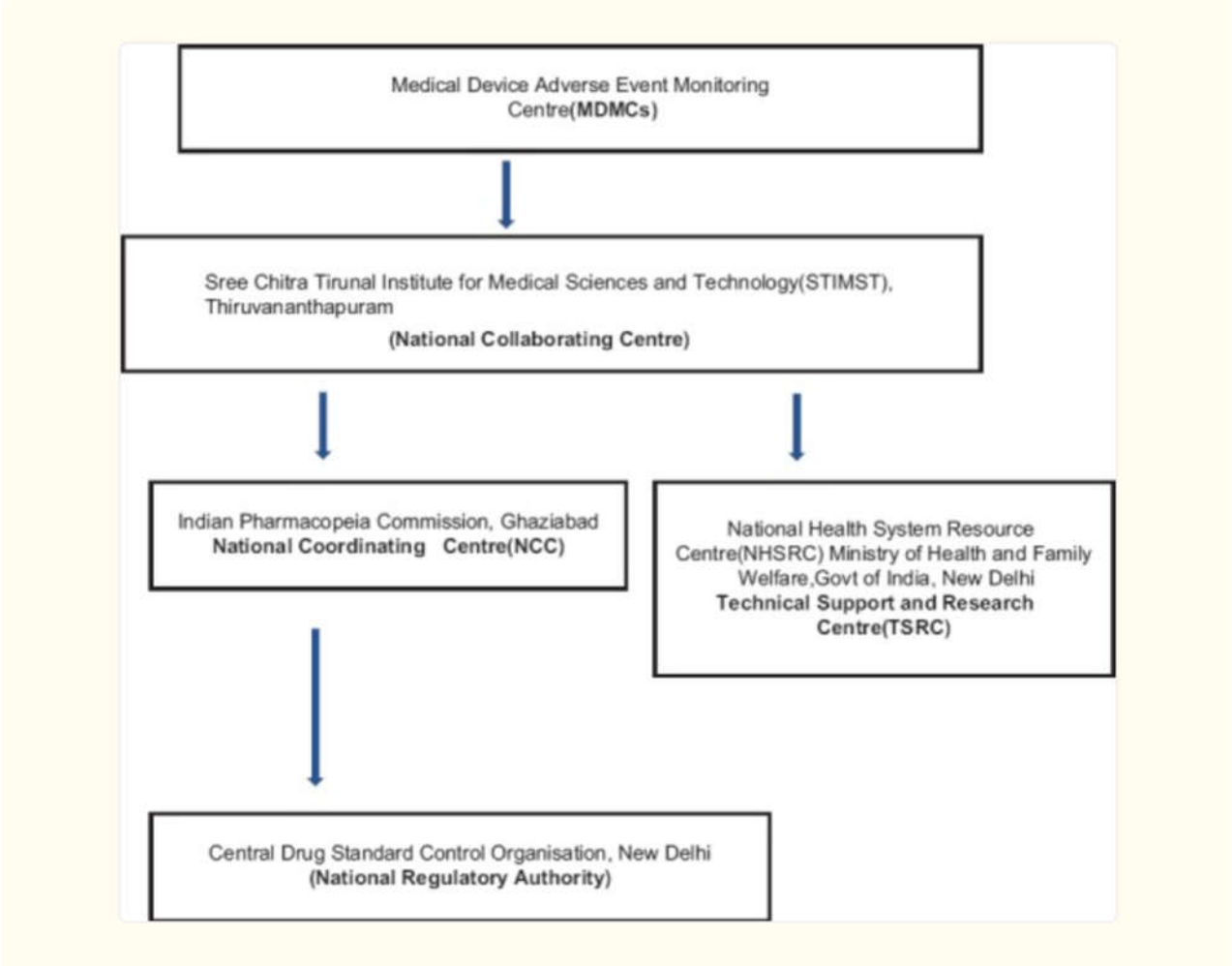

Fig:5 Representation of the administrative structure of materiovigilance (Mv) program of India

- Materiovigilance supports in generating proof-based data on the security and safety of therapeutic devices used in the medical field. It ensures the compliance with relevant regulations and standards.[9]
- Materiovigilance has also resulted to be cost saving. By reducing the costs associated with adverse events due to medical devices, recalls, emergency situations, and regulatory non-compliance, materiovigilance has proved to help in reduction of expenses.[9]
- Collaboration and exchange of vital information and data with other healthcare organizations globally and international agencies further enhances patient safety and reduces the chances of medical device associated adverse effects.[9]

POST- MARKETING SURVEILLANCE

Materiovigilance also has a pivotal role in shaping the post-marketing surveillance also known as pharmacovigilance.

POST- MARKETING SURVEILLANCE (PMS): Post-marketing surveillance which is also known as PHARMACOVIGILANCE refers to the practice of monitoring the safety and performance of a medical device or pharmaceutical drug safety it has been released to the market. The goal is to detect, assess, and minimize potential risks associated with the drug once it is used by the general population. This process helps ensure ongoing safety, identity rare or long-term side effects, and ensure that the benefits of the product continue to outweigh any risks.[10]

Key aspects of pot-marketing surveillance include:

1. ADVERSE EVENT REPORTING: Health professionals, patients, and consumers report any adverse effects or unexpected outcomes related to a drug`s use. This data is collected and analysed by regulatory authorities (like the FDA, EMA, etc..).

2. RISK MANAGEMENT PLANS: Manufacturers may be required to implement strategies to mitigate risks associated with their products, such as restricted distribution programs, additional warnings, or further studies.

3. LONG-TERM EFFICACY AND SAFETY MONITORING: Some side effects or Interactions may not become apparent during clinical trials due to the limited sample size or

controlled conditions. Post-marketing surveillance helps identify such issues by monitoring real-world use.

4. REGISTRY AND COHORT STUDIES: These are used to track the outcomes of drug use over time and help to identify rare adverse events or trends that may not have been evident during pre-market clinical trials.

5. PERIODIC SAFETY UPDATE REPORTA PSURs: Pharmaceuticals companies are required to submit regular on the profile of their products, including any new adverse event data or changes in the benefit-risk profile.

6. SIGNAL DETECTION: Using statistical methods and data mining, regulatory bodies and companies look for "signals" in the safety data that might indicate new or emerging risks associated effects.[10]

IMPORTANCE OF POST-MARETING SURVEILLANCE

- **IMPROVED PUBILC HEALTH:** By identifying and addressing potential issues with drugs, PMS helps to prevent harm and ensure the continued safety of pharmaceuticals products.
- **REGULATORY ACTIONS:** Based on post-marketing data, regulatory may update drug labelling, impose restrictions, or even withdraw drugs from the market.
- **PATIENT SAFETY:** Continuous monitoring ensures that any newly discovered risks are communicated effectively to healthcare providers and patients.
- **IDENTIFICATION OF RARE OR LONG-TERM EFFECTS:** Clinical trials before approval often involve a limited number of participants and may not capture rare or long-term adverse effects. PMS helps identify such risks in a larger, more diverse population over extended periods.
- **PUBLIC CONFIDENCE:** Continuous monitoring and the transparent reporting of safety issues can enhance public trust in the healthcare system and pharmaceutical companies.
- **EARLY DETECTION OF SAFETY ISSUES:** Post-marketing surveillance can quickly identify signals of safety concerns that were not apparent in clinical trials, allowing for swift action like product recalls or safety alerts.

- **COST-EFFECTIVE:** By detecting and addressing safety issues early, post-marketing surveillance can reduce the long-term costs of healthcare, litigation, and regulatory penalties, ensuring a better allocation of resources in public health.[10]

METHODS OF POST-MARKETING SURVEILLANCE:

1. **SPONTANEOUS REPORTING SYSTEMS**: One of the primary mechanisms for collecting post-marketing safety data is through spontaneous reporting by healthcare professionals and patients. Systems like the FAD`s Adverse Event Reporting System (FAERS) and the Vaccine Adverse Event Reporting System (VAERS) allow users to report side effects. These systems play a crucial role in detecting new adverse events that might not have been identified during clinical trials.
2. **REGISTRIES:** Medical product registries collect data from patients who are using a specific product. These registries track outcomes, safety signals, and effectiveness over time, providing valuable insights into the real-world performance of medical interventions.
3. **EPIDEMIOLOGICAL STUDIES:** Post-marketing surveillance often involves large-scale epidemiological studies that follow diverse patient populations over time. These studies are particularly useful for understanding long-term outcomes and detecting rare adverse events that may not have been observed in clinical trials.
4. **PHARMACOVIGILANCE:** Pharmacovigilance refers to the science and activities related to the detection, assessment, understanding, and prevention of adverse effects of drugs. It involves collecting and analysing data from multiple sources, including healthcare databases, literature reviews, and clinical observations.
5. **PATIENT-REPORTED OUTCOMES (PROs):** Gathering patient-reported data helps in assessing how patients perceive the efficacy and safety of a product. PROs provide insights into symptoms, quality of life, and the overall patient experience, which are not always captured in clinical trials.
6. **CHALLENGES IN POST-MARKETING SURVEILLANCE UNDERREPORTING:** One of the main challenges in PMS is underreporting of adverse events. Healthcare professionals and patients may be unaware of or reluctant to report side effects, leading to an incomplete safety profile.
7. **BIAS IN DATA COLLECTION:** Data collected post-marketing may be subject to various biases, including selection bias (as certain patient groups may be

overrepresented or underrepresented) or reporting bias (where more severe adverse events are reported while milder events go unnoticed).

8. **DATA INTERPRETATION:** The vast amount of data collected during post-marketing surveillance can be challenging to analyse. It requires sophisticated tools and expertise to distinguish true safety signals from background noise, particularly in large and complex datasets.
9. **GLOBAL VARIABLITY:** Different countries may have different regulatory frameworks and standards for reporting adverse events. This can create challenges in harmonizing data from multiple sources and ensuring global consistency in product safety monitoring.[10]

REGULATORY OVERSIGHT

- Regulatory agencies like the FDA, EMA, and others play a significant role in overseeing post-marketing surveillance efforts. These agencies:
- Set guidelines for the informing management.
- Require periodic safety update reports (PSURs) from manufacturers.
- Issue safety alerts or product recalls when necessary.[10]

Post-marketing surveillance is vital to ensuring that medical products remain safe and effective throughout their life cycle. By actively monitoring the use of pharmaceutical products and medical devices in real-world settings, regulatory agencies and manufacturers can identify and address safety concerns, improve product labelling, and guide healthcare providers in the optimal use of these products. As healthcare becomes more complex and personalized, post-marketing surveillance will continue to play a key role in safeguarding public health.[10]

REGULATORY COMPLIANCE

Regulatory compliance in materiovigilance refers to the adherence to the obligatory rules and regulations set by the authorities requiring the medical device producers to actively observe and report the unfortunate events associated with their devices post market and taking the mandatory actions to address identifies hazards.[11] Basically, it’s the process of following legal standards set up by the higher authorities to properly manage and report the possible issues after they are sold to the market.[11]

International medical device regulator forum [IMDRF], consisting of ten countries such as the Japan, China, South Korea and India was set up in 2011 to establish the materiovigilance

program to monitor medical devices and its related issues and to coordinate global medical device regulation through Mv.[11]

IMDRF:

A deliberate assembly of medical device regulators from around the globe has converged to establish a robust foundation for the international harmonization task force on medical devices. Their objective is to expedite the process of standardization and transformation.[11]

GHTF:

Formed in the year 1992 and it is an unofficial group created for the convergence in regulations around the world. Members include the following:

- European union
- United state
- Canada
- Australia
- Japan

GHTF dispersed late in 2012. Its commission has been taken over by the IMDRF[11]

Regulations and standards

RC for the medical devices is the process of sticking to the rules and regulations set by the governing bodies such as the FDA, ISO and European commission. The goal of this commission is to verify device safety and working.[11]

- **EU**
- **FDA**
- **ISO**

FDA

The FDA is accountable for ensuring medical devices marketed in the United States are secure and efficacious throughout their entire product lifespan. In fulfilling this responsibility, the FDA fosters the innovation and manufacture of premium-quality medical devices.[11]

ISO

Quality Management Systems

1. ISO 13485: Quality verification frameworks and regulatory mandates.

2. ISO 13485:2016: Revision of the standard, emphasizing risk assessment and regulatory adherence

Risk Management

1. ISO 14971: Application of risk management to medical devices.

2. ISO/TR 24971: Guidance on the application of ISO 14971

Clinical Evaluation and Investigation

1. ISO 14155: clinical research of medical devices for human subjects

2. ISO/TR 20416: direction on the application of ISO 14155[11]

Consequences of Non-compliance

Non adherence with medical device standards can result in devastating repercussions, including:

- Brand tarnishment
- Substantial monetary fines
- Possible litigation
- Patient injury due to defective devices
- Mandatory product retrieval
- Voluntary market exit
- Official regulatory scrutiny
- Erosion of customer confidence

All these consequences arise from failing to meet the requisite safety and quality benchmarks for medical devices.[11]

Hence, regulatory adherence is vital for medical devices producers to guarantee the safety and efficacy of their products. Conformity with regulations, such as FDA guidelines, EU and ISO standards help prevent undesirable events, product withdrawals and Reputational tarnish.[11]

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