Medical Device Adverse Event Reporting System using Artificial Intelligence (AI) and Large Language Models (LLM) Techniques.

INTRODUCTION

An unexpected incident during or as a result of "patient use" of a medical device can be defined as an adverse event. Undesired clinical symptoms, such as unexpected test results, unplanned sickness or injury, or unfavourable medical events can all be considered adverse events (AEs).

Importance of Medical Device Adverse Events Reporting:

Despite their rigorous manufacturing, medical equipment cannot guarantee a zero per cent failure rate. In order to ensure patient safety and improve medical devices to the point where they could be used in creating new ones, adverse event monitoring of medical devices at healthcare practices is essential. Similar surveillance initiatives like the IRIS inSite project in Australia, the MedSun program in the United States, and the Canadian Medical Devices Sentinel Network (CMDSNet) program in Canada have shown that many nations understand the value of keeping an eye on adverse events related to medical devices and the involvement of healthcare professionals as practical ways to reduce the risk of harm from medical devices and improve public health.

Common adverse events include foreign particles floating through IV fluid, injection errors in infusion pumps, issues with contact lens wearers, removing broken devices, a device's remaining piece, and the dislodged coronary stent.

The Food and Drug Administration (FDA) research states that less than 0.5% of medical device negligence instances were officially reported.

Underreporting adverse occurrences related to medical devices results in missed opportunities to gather information that could be utilized to stop similar incidents from happening again or opportunities that could be handled as pertinent data for the advancement of medical devices.

Fear of penalty or censure, ambiguity about what should be reported, lack of time, and the intended use of incident reports are the four key obstacles to event reporting in a medical context.

Benefits of Reporting:

Healthcare professionals who use medical devices to provide patient care can readily report adverse occurrences related to those devices.

Reporting's contribute to increased medical device safety such as Early safety issue detection, Determination of device faults or failures, and Assessment of the efficiency and performance of the device.

It enhances regulatory supervision and surveillance; preventing injury and probable fatalities, enabling prompt safety notifications or recalls.

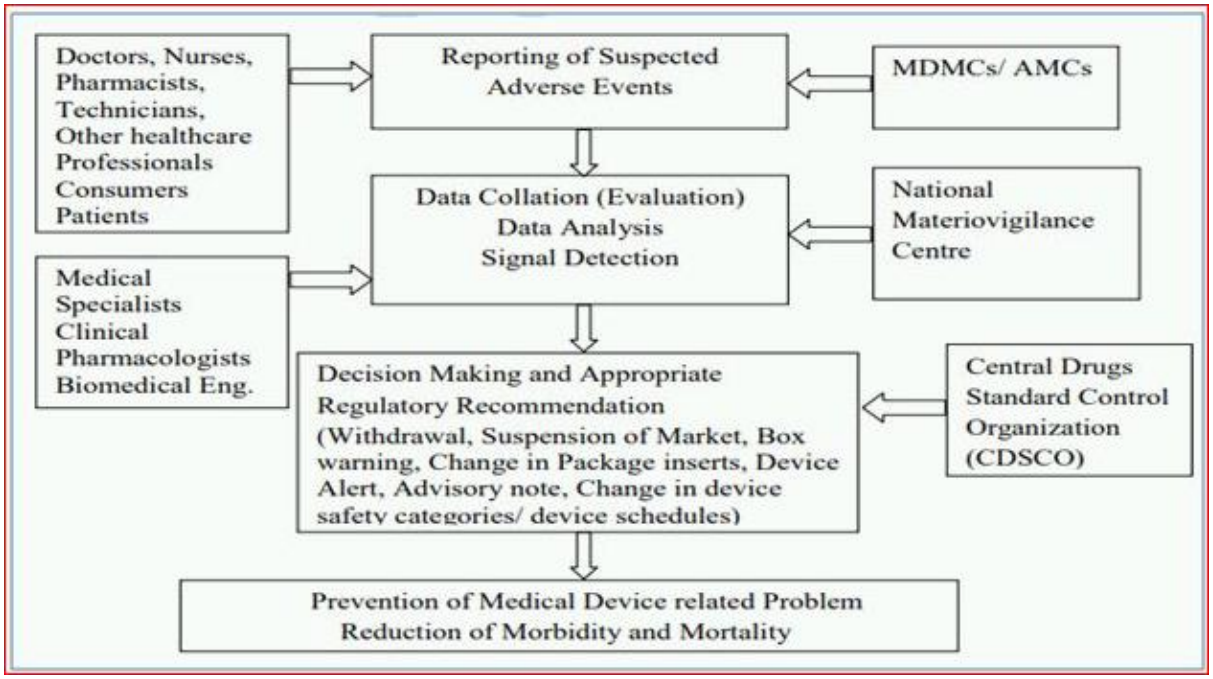
For medical practitioners it Improves professional expertise and education, Reinforcing evidence-based judgment, transparency and accountability in the medical field.
The value of patient reporting encourages patients to take an active role in their treatment, Offering distinctive perspectives on adverse occurrences connected to devices, Helping to advance the development of upcoming medical devices.

Initiatives from Govt. of India :

On July 6, 2015, the Materiovigilance Programme of India (MvPI) was approved by the Ministry of Health and Family Welfare, Government of India. Since 2018, the Indian Pharmacopoeia Commission (IPC) has served as the MvPI National Coordination Center (NCC). The Central Drugs Standards Control Organization (CDSCO), New Delhi, supports MvPI with experience acting as a national regulator; Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, serves as the National Collaboration Center; and the National Health System Resource Centre (NHSRC), New Delhi, serves as the Technical Support Partner.

The goal of the Materiovigilance Programme of India (MvPI) is to gather adverse events related to medical devices and analyze them in a methodical, scientific manner to support regulatory decisions and suggestions for the safe use of medical devices

The current adverse event reporting system of MvPI



Various modalities to report the MDAEs

1. **Medical Device Adverse Event (MDAE) Reporting Form-**
2. **Mobile Application-**
3. **Number- Helpline- Toll Free**
4. **MvPI Letter of Intent-**

Medical Device Adverse Event (MDAE) Reporting Form-

Details about adverse events, their severity, date, location, device category, model name of the organization's available device, its use following the event, name of the medical device, manufacturers, brand names, model number, serial number, batch number, instrument catalogue number, date of installation/implantation/explanation, list of accessories, and other pertinent information, such as actions taken right away after the incident or event, are all included in the reporting form.

The Health Ministry's recommendations included establishing uniform protocols for receiving, recording, and looking into complaints; creating a comprehensive reporting form and structure; figuring out when complaints need to be reported and how to generate reports on it; closing complaints and updating the risk management file; and avoiding reporting the same incident twice.

The MvPI is designed to make it feasible to collect safety data in an organized way, allowing data produced in India to serve as the basis for regulatory decisions and suggestions for the safe use of medical devices in India. This is also going to result in the industry's prevalent challenges being addressed systematically.

Limitations on the Current Reporting System:

Developing a strong Materiovigilance system to monitor adverse events associated with medical devices throughout their full life cycle is critical for ensuring patient safety. To implement regulatory actions or corrective measures to assure safety, the review process should start at the design phase and extend until post-marketing. To be more effective, the risk assessment of the incidents that have been reported should be carried out on an ongoing basis.

Events are captured via the MDAE reporting form, which stakeholders fill up using text data, mobile apps with a backend database, voice messages received on a toll-free number, etc. The reporting mechanisms are available in a variety of forms and are very detailed. Since the pandemic, there has been an increase in the reporting of MDAEs associated with PPEs, pulse oximeters, digital thermometers, digital blood pressure monitors, etc. Because of increased human participation, the traditional methods of evaluating the AEs would be laborious and susceptible to inaccuracy.

Proposed Methodology of Reporting Using AI and ML in the Materiovigilance Programme

The current reporting procedure needs to be upgraded with cutting-edge technologies like AI and ML from gathering data phases through the review, baseline assessment, CAPA on events, etc. to make it fast, accurate, scalable and reliable.

Artificial Intelligence (AI) has applications in speech-to-text, natural language processing (NLP), image processing, process automation, information collection utilising automated data obtained through APIs connected to the Device Database, integration into multiple public online databases, and more. These tools can even extract pertinent information and improve the analysis of both structured and non-structured data.

The current practice is to report problems and grievances using social media sites like Facebook, Twitter, YouTube, and LinkedIn. This method, when combined with a particular NLP model, would be a faster and more scalable approach to compile unpleasant events.

The accuracy and calibre of reporting could be increased by employing AI technologies to gather information, utilizing machine learning techniques and semantic search optimization. AI's predictive modelling will assist us in controlling the recurrence of AE and improve productivity.

By using these technologies, the reporting culture would be strengthened, a robust reporting framework that satisfies regulatory requirements could be provided at a reasonable cost, and the patient experience would be improved.

Scope of the Project:

1. Web-based Reporting Tool with Role Based Access Control for Admin, Healthcare Professionals, Manufacturers, Consumers, Patients etc.
2. Speech to Text - To convert native speech or audio with adverse events into text.
3. Natural Language Processing (NLP) - The user can discuss the event in their own language. English text will be produced by the NLP model.
4. Image to Text (OCR) - This feature automatically fills in the relevant field by extracting data from the medical device or consumables' outer cover or package.
5. Data mining: Look through social media platforms and public databases to find information that corresponds to medical device adverse events nationwide or internationally. This information can then be added to databases or used to effectively create alerts and recalls.
6. Machine Learning tools for Predictive Analysis: These tools use data collected for Base line studies and CAPA to forecast signals and adverse events.
7. Chat Bots / Assistive Tools: These bots or tools can be used for FAQs and curated Knowledge across stakeholders.
8. Large Language Models: With the data available with MvPI and other International Databases, Develop LLMs and build intelligent systems on top of those models.
9. Dashboard with filters to give a multi-dimensional view of the no of events raised by
   • Users/Consumers

- Medical Practitioners
- Device types, etc.