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Assesment of Knowledge about Materiovigilance among Pharmacy Students

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ABSTRACT: Medical device have long been essential lifesaving tools and are widely used around the world. Materiovigilance (Mv) shares the same purpose and approach as Pharmacovigilance (Pv) in ensuring patient safety, but it focuses specifically on Medical Devices associated with Adverse Events (MDAEs) and their monitoring. The MvPi in India was launched on july 6, 2015, at the Indian Pharmacopoeia Commission (IPC)The aim of the study was to assess the knowledge about materiovigilance among the pharmacy students. This descriptive, cross-sectional study utilized a questionnaire - based approach and was conducted among pharmacy students in Salem, Tamil Nadu. A self-administered questionnaire was developed by me using Google forms in English to collect data on the study variables. The questionnaire contained a total 15 questions related to knowledge about materiovigilance. The data were systematically collected and rigorously analysed using statistical techniques. Total 300 responses when received through google form. Among the 11 question are MCQ type and 4 question are yes/no type. Increased awareness and education about materiovigilance are essential for effective monitoring and response to adverse events. By fostering a culture of proactive reporting and continuous learning, healthcare systems can enhance the safety and efficacy of medical devices, ultimately leading to better patient care and outcomes.

KEYWORDS: Medical devices, Adverse events ,Materiovigilance, Pharmacy students, Medical Device Adverse Events Reporting Form.

I. INTRODUCTION

INDIAN PHARMACOPOEIA COMMISION:

- IPC stands for Indian Pharmacopoeia Commission, which is an autonomous institution under the Ministry of Health and Family Welfare.[1]
- The Indian Pharmacopoeia Commission is responsible for setting standards for all drugs manufactured and sold in India and publishing the Indian Pharmacopoeia.[2]
- It was formed in 1956 according to the Indian Drug and Cosmetics Act at 1940.[1]
- The IPC publishes new editions of the IP every few years,with the latest edition being the ninth edition in 2022.[3]

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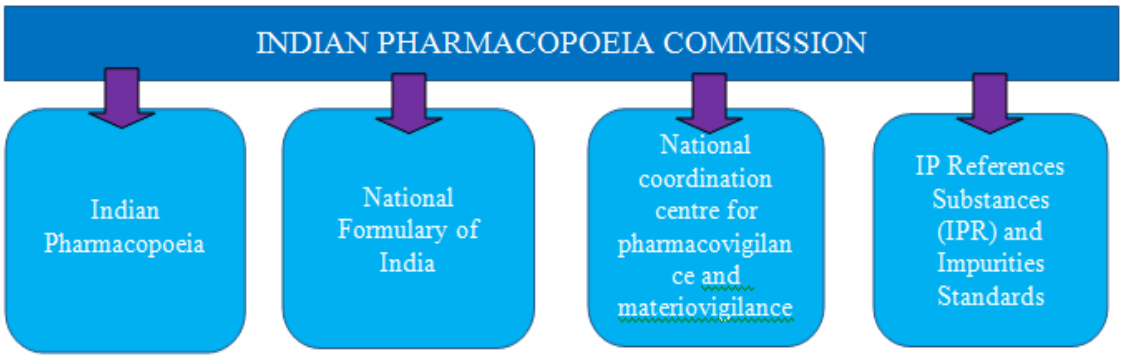

MATERIOVIGILANCE:

Materiovigilance is the study of adverse events associated with the use of medical devices. The term "vigilance" means close monitoring of the possible adverse effects. [4]

Materiovigilance is a system used to monitor and evaluate the safety and performance of medical devices. It involves tracking any adverse events or issues associated with these devices, analysing their impact, and reporting findings to ensure patient safety and improve device performance.[5]

SCOPE OF MATERIOVIGILANCE:

- To enhance patient safety and reduce the occurrence of incidents, thus improving health protection for patients, users, and others.
- To assess the suggested framework and its impact on the global harmonization of the Indian medical device vigilance system, specifically the Global Harmonization Task Force (GHTF).
- To address challenges and enhance the efficiency of equipment use and productivity.
- To establish a nationwide system for monitoring patient safety.
- To assess the risk-benefit ratio of medical devices in use.
- To assist the Central Drugs Standard Control Organization (CDSCO) in making informed decisions regarding medical device usage.
- To disseminate safety information about medical device usage to various stakeholders in order to minimize risks.
- To raise awareness among stakeholders about the importance of reporting medical device adverse events (MDAE).[4]

MATERIOVIGILANCE PROGRAMME OF INDIA(MvPi):

In India, medical devices are governed by the Drugs and Cosmetics Act of 1940 and the Rules of 1945. In 2017, the Government of India, working with the Drug Technical Advisory Board (DTAB), established the Medical Devices Rules to regulate their import, manufacture, sale, and distribution.[6]

The Materiovigilance Program of India (MvPI) was launched on July 6, 2015, at the Indian Pharmacopoeia Commission (IPC) in Ghaziabad by the Drug Controller General of India (DCGI).[7]

These rules were officially notified on January 31, 2017, and came into effect on January 1, 2018.[6]

The Indian Pharmacopoeia Commission (IPC) serves as the National Coordination Centre (NCC) for the MedicalDevicesAdverse Event Monitoring System.

The MvPI aims at monitoring adverse events associated with the medical devices (medical device associated adverse events) The Sree Chitra Institute for Medical Sciences and Technology (SCTIMST) operates as the designated National Collaborating Centre, while the Central Drug Standard Control Organisation (CDSCO) acts as the regulatory authority for MvPI. Technical support is provided by the National Health System Resource Centre (NHSRC).[4]

Medical Device Adverse Event Monitoring Centres (MDMCs) have been established to create awareness about the programme and enhance the quality of reporting.[8]

In 2024, underMvPI a total of 451 MDMCs have been identified in the country to report the adverse events associated with the use of medical devices, purely on voluntary basis. A standard reporting format called 'Medical Device Adverse Event Reporting Form'.

In order to successfully implement MvPI, it is important to integrate the biomedical engineering department at hospitals and institutions, as well as

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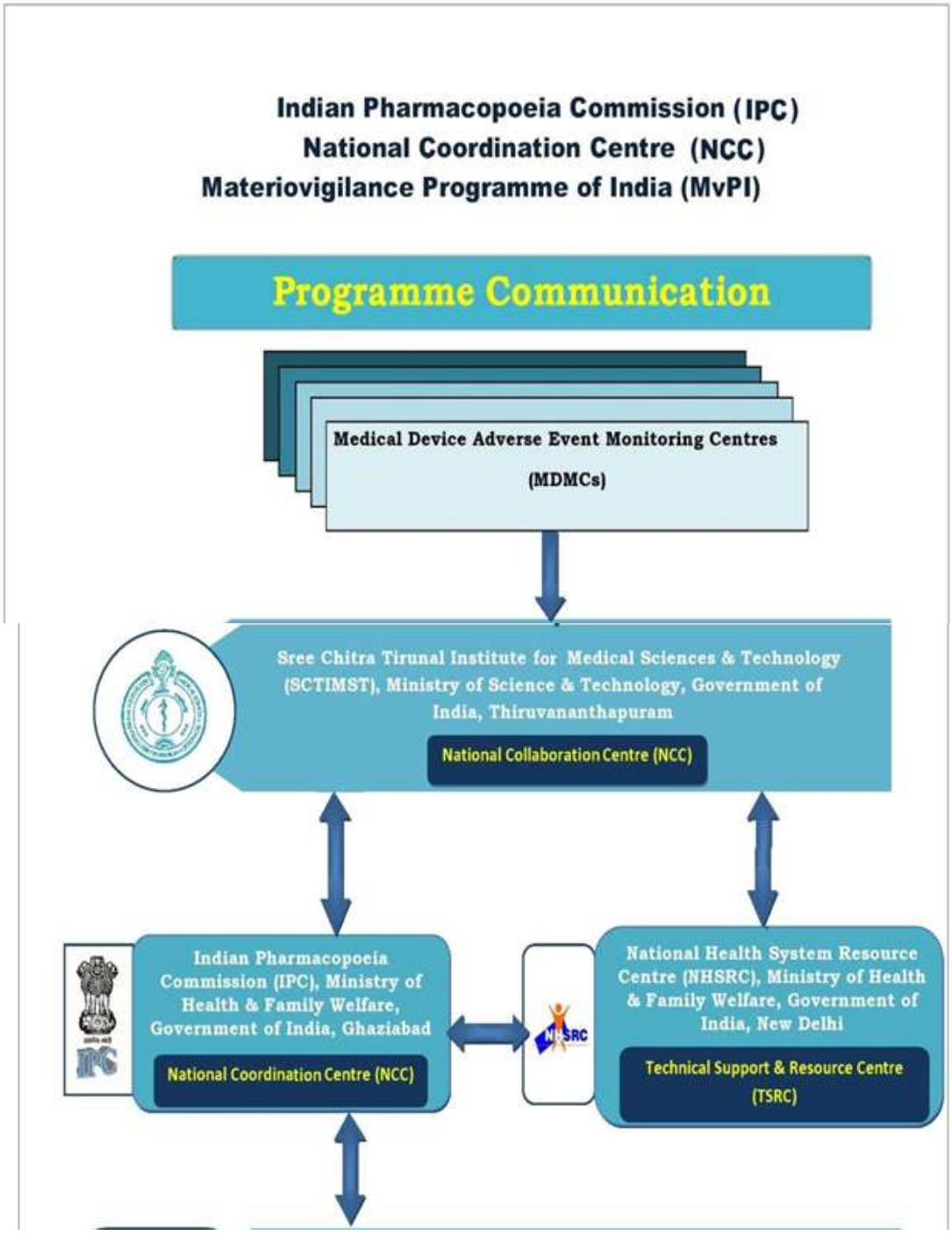
coordinate with other departments. Institutes with a biomedical/clinical engineering department (BMED) are given priority to serve as medical device adverse event monitoring centers (MDMCs). Other departments are also considered if they are connected to BMED.[5]

The involvement of BMED in MvPI is crucial because most of the medical devices are designed/manufactured with engineering technology.[5]



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VISION:

To improve patient safety and welfare of Indian population by monitoring adverse events related to medical devices and thereby reducing risk associated with use of medical devices.[8]

MISION:

To protect the health of the Indian Population by ensuring that the benefits derived from the use of medical devices substantially outweigh the associated risks.[8]

OBJECTIVE:

The main objective of the MvPI is to streamline the process of gathering and evaluating data in order to ensure that regulatory determinations regarding the safe utilization of medical devices in India are grounded in evidence.[9]

CLASSIFICATION OF MEDICAL DEVICES:

CLASS	RISK	EXAMPLE
A	Low risk	Cotton wool, Surgical dressing, Thermometer
B	Low – moderate risk	Hypodermic needle, suction equipment
C	Moderate – High risk	Lung ventilator, Bone fixation plate
D	Very High risk	Heart valve, Pacemaker, MRI Machine

What is medical device?

The World Health Organization (WHO) defines a medical device as any instrument, implement, machine, apparatus, material, reagent for in vitro use, software, or other related article intended by the manufacturer to be used, alone or in combination for prevention, diagnosis, treatment, or alleviation of disease or injury.[10]

Today, there are estimated 2 million different kinds of medical devices on the world market, categorized into more than 7000 generic devices groups.[11]

Purpose of medical device:

- Prevent or reduce the risks of medical conditions or disease.
- Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation, of or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy or of a physiological process supporting or sustaining life.
- Control of conception.[12]

Who can report?

- Clinical specialist
- Pharmacist
- Biomedical/clinical engineers
- Nurse
- Patient
- Hospital technology manager
- Technician
- Medical device manufacturers/importers/distributor.

METHODS AND MATERIALS:

This descriptive, cross-sectional study utilized a questionnaire - based approach and was conducted among pharmacy students in salem, Tamilnadu from 5thjuly 2024 to 5th august 2024. This study aimed to evaluate their knowledge, attitudes and practices regarding materiovigilance. A self-administered questionnaire was developed by me using Google forms in english to collect data on the study variables. The initial iteration of the

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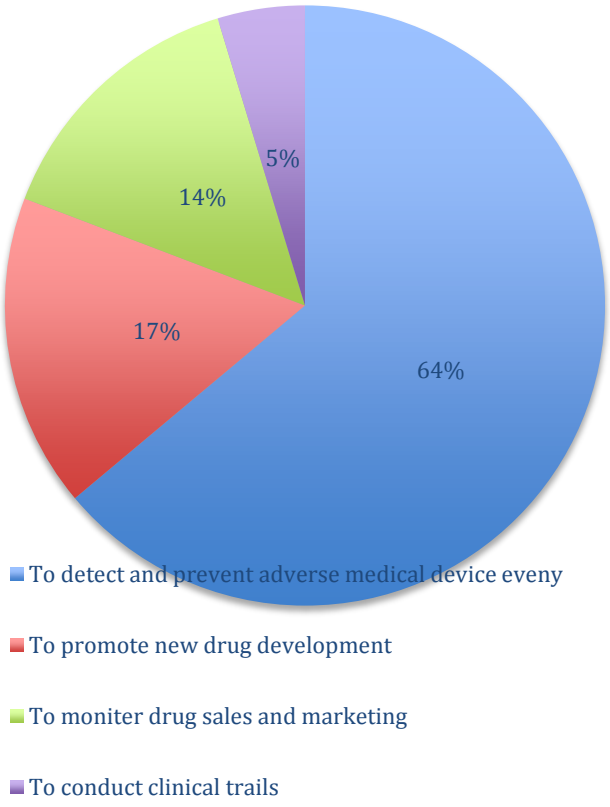
questionnaire was meticulously crafted to ensure accurate and comprehensive data collection. Our survey consists of 15 questions on knowledge of materiovigilance, MVPI, IPC, CDSCO, NPP. The 15-question survey consisted of 11 multiple-choice questions and 4 yes/no questions, all of which were mandatory. Responses were scored as either 1 (correct or positive) or 0 (incorrect or negative). The assessment aimed to evaluate students' understanding of materiovigilance, MVPI, NPP, and CDSCO-related concepts. The results of this survey can provide valuable insights into the knowledge and awareness of pharmacy students in these critical areas. The data were systematically collected and rigorously analyzed using statistical techniques.

II. RESULT:

Total 300 responses when received through google form.Among 15 questions ,9 questions related to assess the knowledge about Materiovigilance and remain 6 questions set related to MateriovigilanceProgrammeof India ,NCC,Central drug standard control organization(CDSCO),Medical device adverseEvents.Among the 11 question are MCQ type and 4 question are yes/no type

1.What is the primary role of Materiovigilance?



Out of 300 stdents surveyed about the primary role of materiovigilance, 192 students (63.9**%)** answered correctly and108 (36.1%) answered incorrectly. It indicates that most of the students known the primary role of materiovigilance.

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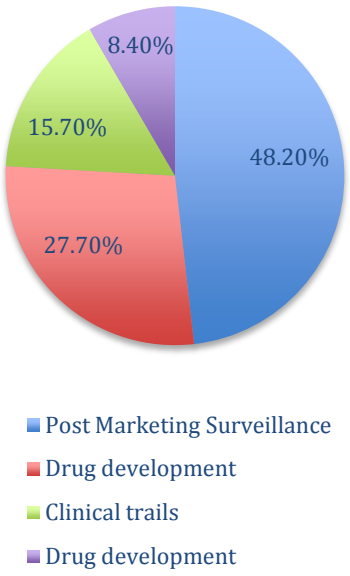
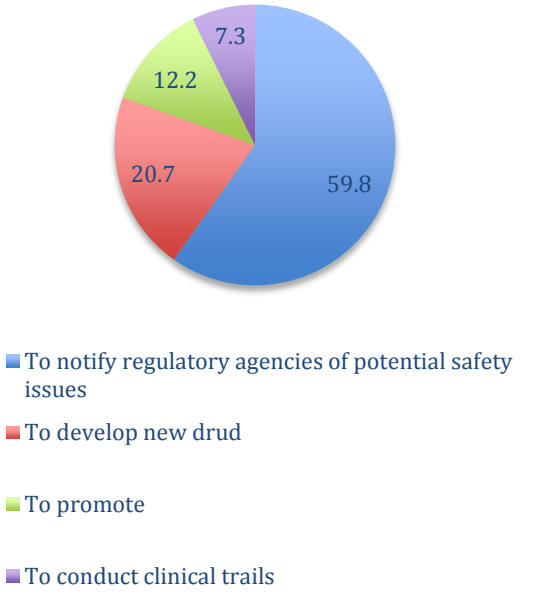
2. Which of the following is a key component of materiovigilance?



Out of 300 students surveyed about the key component of materiovigilance,145 students (48.2%) answered correctely,while 155 students (51.8%)answered incorrectly.it indicates most of students don't known the key component of materiovigilance.

3.What is the purpose of reporting adverse device event in materiovigilance?



Out of 300 students surveyed about the purpose of reporting adeverse events in materiovigilance, 179(59.8%) answered correctly, while 121(40.2%) answered incorrectly.This indicates most of students poor knowledge about the purpose of reporting adverse events.

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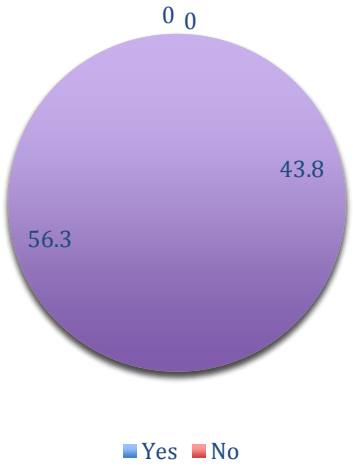
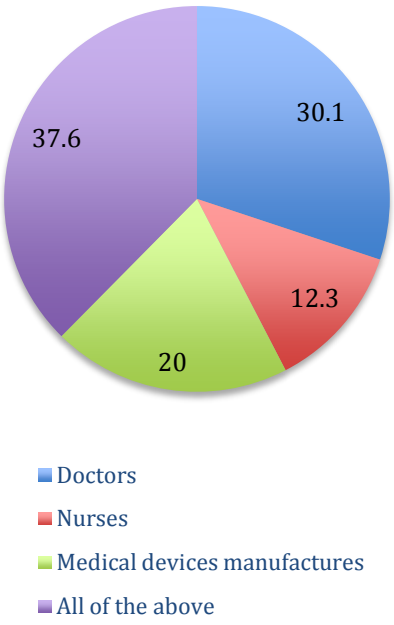
4.Are Materiovigilance and Pharmacovigilance are same?



Out of 300students surveyed about materiovigilance and pharmacovigilance are same, 131students (43.8%)answered correctly while 169students (56.3%)answered incorrectly. This indicates that most students have poor knowledge about materiovigilance and pharmacovigilance.

5. Who can report a medical device -induced adverse event?



Out of 300 students surveyed about who can report a medical device-induced adverse event, 113(37.6%) answered correctly, while 187(62.4%) answered incorrectly. This indicates that most students have poor knowledge about reporting medical device-induced adverse events.

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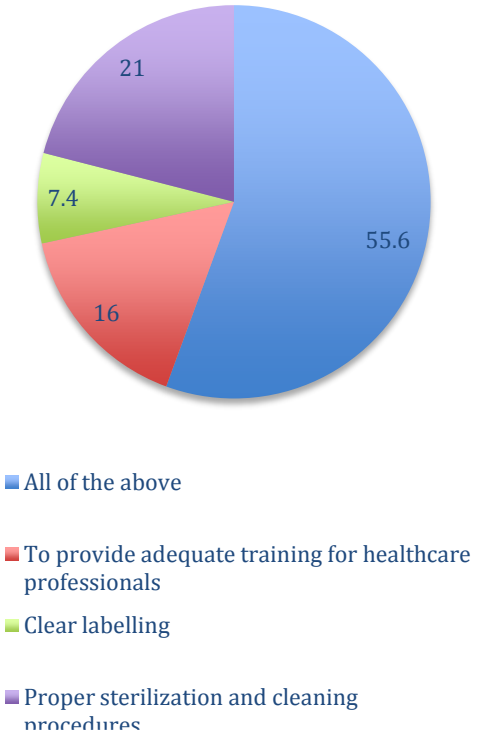
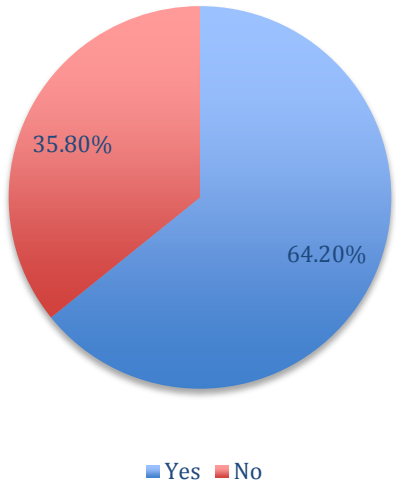
6.How can adverse events in medical device be reduced?



Out of 300 students surveyed on how to reduce adverse events in medical devices, 167 (55.6%) answered correctly, while 133 (44.4%) answered incorrectly. This suggests that most students have a limited understanding of how to mitigate adverse events in medical devices.

7.Is IPC is an autonomous instiution?



Out of 300 students surveyed about whether the IPC is an autonomous institution, 192 (64.2%) answered correctly, while 108 (35.8%) answered incorrectly. This indicates that most students have a fair understanding of the IPC.

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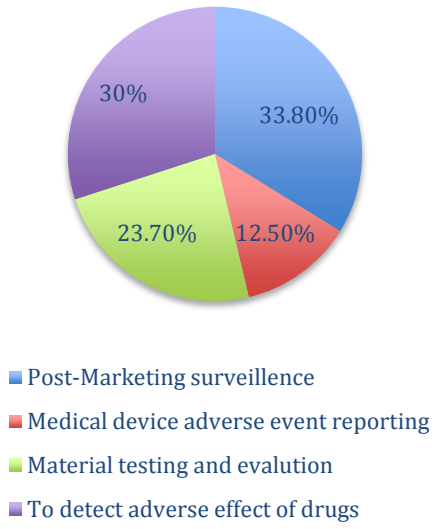
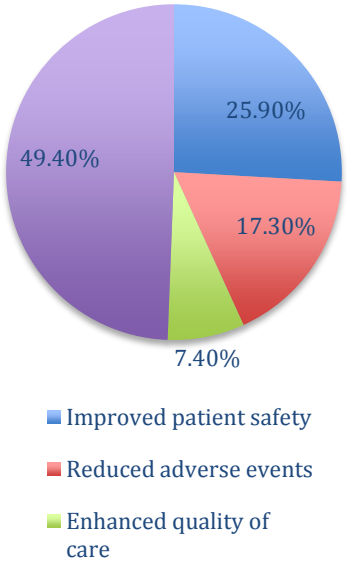
8.Which of the following is NOT included in materiovigilance?



Out of 300 students surveyed about what is not included in materiovigilance, 90(30%) answered correctly, while 210 (70%) answered incorrectly. This indicates that most students have poor knowledge about materiovigilance.

9.What are the benefit of effective materiovigilance?



Out of 300 students surveyed about the benefits of effective materiovigilance, 148 (49.4%) answered correctly, while 152 (50.6%) answered incorrectly. This indicates that most students have sufficient knowledge about the benefits of effective materiovigilance.

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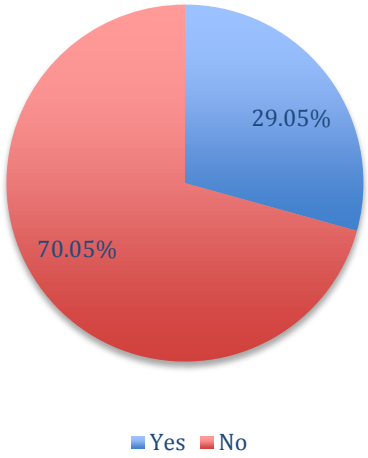
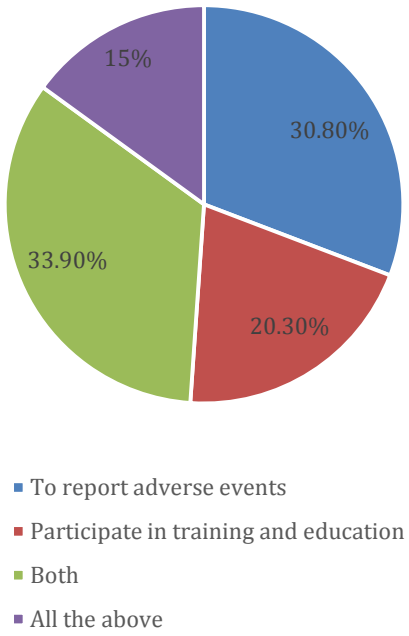
10.Have you checked out the form for reporting adverse events related to medical devices ?



Out of 300 students asked whether they have checked out the reporting form for adverse events, 87 students (29.05%) answered correctly, while 213(70.05%) answeredincorrectly. This indicates that most students have not checked out the reporting form for adverse events.

11.What is the role of healthcare professional in materiovigilance?



Out of 300 students surveyed about the role of healthcare professionals in materiovigilance, 102 (33.9%) answered correctly, while 198(66.1%) answered incorrectly. This indicates that most students have poor knowledge about the role of healthcare professionals in materiovigilance.

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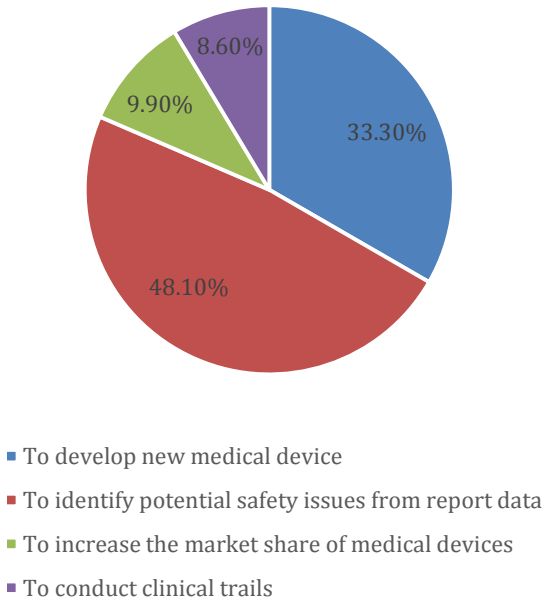
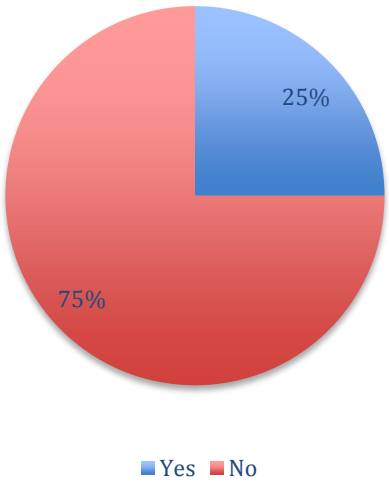
12.What is the role signal detection in materiovigilance ?



Out of 300 students surveyed about the role of signal detection in materiovigilance, 144 (48.1%) answered correctly, while 156 (51.9%) answered incorrectly. This suggests that most students have a fair understanding of the role of signal detection in materiovigilance.

13.Does India have specific guidelines for Materiovigilance Programme of India MvPI?



Out of 300 students surveyed about whether India has specific guidelines for MvPi,75 students (25%) answered correctly, while 225 students(75%) answered incorrectly. This indicates that most students have poor knowledge about Indiaspecific guidelines for MvPi.

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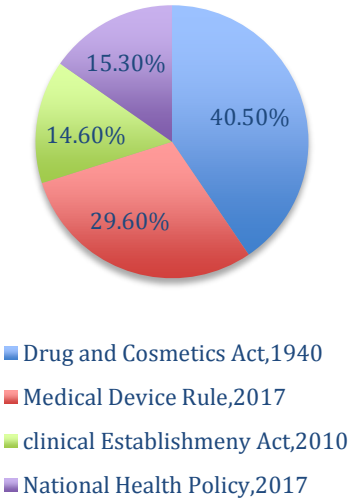
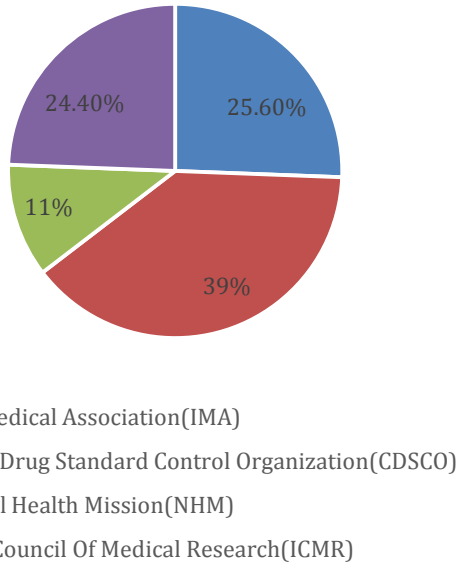
14.Which document provide the regulatory framework for medical devices in India?



Out of 300 students surveyed about the document that provides the regulatory framework for medical devices in India, 89students (29.6%) answered correctly, while 211 students(70.4%) answered incorrectly. This indicates that most students have sufficient knowledge about the document providing the regulatory framework for medical devices in India.

15.Who is responsible for managing the Materiovigilance Programme of India (MVvPI)?



Out of 300 students, 117 students (39%) answered correctly about who is responsible for managing the MvPi, while 183 students (61%) answered incorrectly. This shows that most students have poor knowledge about managing the MvPi.

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OVERALL RESULT:

Total 300 responses collected via google form,Total 15 questions,11 questions are multiple-choice questions(MCQs)and 4 questions are YES/NO.Out of 300 responses, 43% answered correctly, and the majority, 56%, answered incorrectly. This means approximately 129 students answered correctly and 171 students answered incorrectly.

S.NO	MCQ TYPE QUESTIONS	CORRECET RESPONSE(%)	INCORRECT RESPONSE(%)
1.	What is the primary role of Materiovigilance?	63.9%	36.1%
2.	Which of the following is a key component of materiovigilance?	48.2%	51.8%
3.	What is the purpose of reporting adverse device event in materiovigilance?	59.8%	40.2%
4.	Who can report a medical device - induced adverse events?	37.6%	62.4%
5.	How can adverse events in medical device be reduced?	55.6%	44.4%
6.	Which of the following is NOT included in materiovigilance?	30%	70%
7.	What are the benefit of effective materiovigilance?	49.4%	50.6%
8.	What is the role of health care proffesionalin materiovigilance ?	33.9%	66.1%
9.	What is the role signal detection in materiovigilance ?	48.1%	51.9%
10.	Who is responsible for managing the Materiovigilance Programme of India (MVvPI)?	39%	61%
11.	Which document provide the regulatory framework for medical devices in india?	29.6%	70.4%
	YES/NO TYPE QUESTIONS		
12.	Are Materiovigilance and Pharmacogilance are same?	43.8%	56.3%
13.	Is IPC is an autonomous institution?	64.2%	35.8%
14.	Have you checked out the form of reporting adverse events related to medical devices?	29.05%	70.95%
15.	Does India have specific guidelines for MvPI?	25%	75%

Based on the provided information,43% of the students have adequate knowledge,while a majority of 56% have insufficient knowledge regarding materiovigilance.

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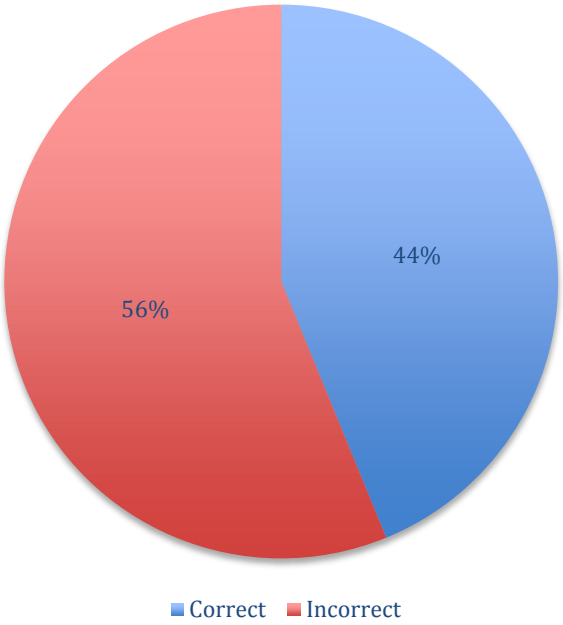
III. DISCUSSION:



Materiovigilance is the process of monitoring,assessing,and preventing adverse events related to medical devices to ensure patient safety. Its primary goal is enhance the patient safety and promote the effective use of medical devices by identifying and mitigating risks.This study, which was based on a questionnaire completed by pharmacy students, found that the majority have only a basic understanding of the term "materiovigilance." Most students were unaware of the National Pharmacovigilance Programme (NPP), the Materiovigilance Programme of India (MVPI), and the Central Drug Standard Control Organization (CDSCO). Most of them don't know the medical device adverse events reporting form.

IV. CONCLUSION:

An assessment of knowledge about materiovigilance typically involves evaluating awareness among healthcare professionals regarding the identification, reporting, and prevention of device-related adverse events. The study indicates that pharmacy currently have limited knowledge regarding materiovigilance and the reporting of adverse events.This highlights the urgent need for regular educational programms or trainings to enhance their awareness.Materiovigilance authorities should design and implement targeted intervention programs to boost pharmacistsknowledge and awareness of adverse event reporting. The study highlights the need for enhanced materiovigilance activities in TamilNadu through ongoing education and training. Furthermore, the government should establish multiple materiovigilancecenters in each district to advance the field.By fostering a culture of proactive reporting and continuous learning, healthcare systems can enhance the safety and efficacy of medical devices, ultimately leading to better patient care and outcomes.Implementing these measures will allow for ongoing monitoring and management of adverse events, which will help reduce the mortality rate caused by such events.

ACKNOWLEDGEMENT:

We extend our sincere thanks to the pharmacy students for their participation in this study on materiovigilance. Your input has been invaluable in assessing current knowledge levels and identifying areas for improvement. We also express our gratitude to our mentors for their guidance and support throughout the study.

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