STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICE OF MATERIOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN SOUTH INDIA

A dissertation submitted in partial fulfilment of the requirements for the MSc in Pharmaceutical Business and Technology

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August 2023

CANDIDATE DECLARATION

I hereby declare that the dissertation entitled “Study on Knowledge, Attitude and Practice of Materiovigilance among healthcare professionals in South India” submitted in the partial fulfilment of MSc in Pharmaceutical Business and Technology is the result of my own work and due acknowledgment given, where reference is made to others work.

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ACKNOWLEDGEMENT

First and foremost, I thank GOD ALMIGHTY, for showering his grace and blessings for this thesis work's successful and timely completion.

It gives me great pleasure to express my deep sense of thanks to my supervisor, Eucharia Aisosa Edegbe for her constant support, motivation, encouragement and valuable suggestions from the very beginning to the end.

I extend my sincere thanks to the entire staff of Pharmaceutical Business and Technology for providing me with all the facilities and support for the successful completion of my thesis.

I am extremely thankful to all the healthcare professionals who participated and shared my survey.

A special thanks to my parents for their constant support and prayers which sustained me thus far. I would like to thank my brother and friends back home for their tremendous support and encouragement.

Table of Contents:

TABLE OF FIGURES:

LIST OF TABLES:

LIST OF ABBREVIATIONS:

AMC: Adverse Event Monitoring Center

KAP: Knowledge, Attitude and Practice

MvPI: Materiovigilance Program of India

CDRH: Center for Devices and Radiological Health

CDSCO: Central Drugs Standards Control Organization

CFDA: China Food and Drug Administration

CFR: Code of federal regulations

FDA: Food and Drug Administration

FSCA: Field Safety Corrective Action

GHTF: Global harmonization task force

HPRA: Health Products Regulatory Authority

ICU: Intensive Care Unit

IPC: Indian Pharmacopoeia Commission

IMRDF: International Medical Device Regulators Forum

MDAE: Medical Device Adverse Event

MDMC: Medical Device Adverse Event Monitoring Center

MedSun: Medical Product Safety Network

MHRA: Medicines and healthcare products regulatory agency

NCA: National Competent Authority

NCC: National Coordinating Center

OAT: Oral Appliance Therapy

SCTIMST: Sree Chitra Tirunal Institute for Medical Sciences and Technology Thiruvananthapuram

TGA: Therapeutic Goods Administration

WHO: World Health Organization

ABSTRACT:

Recently medical devices have been widely used. However, there were several incidents of medical device adverse events across the globe which were even life-threatening. Materiovigilance involves the identification, monitoring and prevention of medical device adverse events. In India, hip implant adverse events and deaths due to incubators led to the implementation of Materiovigilance Programme of India (MvPI). The healthcare professionals must have sufficient knowledge and awareness for proper practice of materiovigilance to ensure patient safety. The research objective was to evaluate the level of knowledge, attitude and practice of materiovigilance among doctors, dentists, nurses and pharmacists in South India and to explore the gaps in the current materiovigilance process. The study identifies strategies and recommendations to improve the process. The study was conducted using a quantitative survey-based method, using a questionnaire prepared in Google Forms. The survey link was shared with healthcare professionals and the participants were sampled randomly. 210 healthcare professionals responded to the survey. The data was analyzed statistically using SPSS software. Only 37.8% of participants were aware of the Materiovigilance Program of India (MvPI). The knowledge about the reporting process and materiovigilance regulations was very low. However, the participants had a high positive attitude. Medical device adverse events were reported by 15% of participants and 98.2% were not trained in materiovigilance. Overall, the participants had below average knowledge and the practice of materiovigilance was very poor among healthcare professionals in South India. A positive correlation of 0.288 with a P value <0.001 was identified between knowledge and practice using the Pearson correlation test. The knowledge, attitude and practice scores among healthcare professionals were compared using Kruskal-Wallis test. The main gaps in the process were lack of training and lack of knowledge of reporting processes and the participants suggested further training and education. The present study focused on opinions for improvement from the healthcare professionals themselves which could be implemented practically by the hospitals or regulatory bodies. Future research could be based on activities to improve the knowledge and practice of materiovigilance.

KEYWORDS: Materiovigilance, Doctors, Nurses, Materiovigilance Programme of India, Dentists, Pharmacist, Medical device adverse event.

CHAPTER 1: INTRODUCTION

Medical devices include a wide variety of equipment, implements, machines and instruments from simple surgical dressings to life-saving devices. Examples of medical devices include pacemakers, implants and stents. Types of medical devices based on the World Health Organization (WHO) are listed in below **Table 1** (WHO, 2023).

TYPE	EXAMPLE
Single use devices	Syringe
Implant	Hip implant, pacemaker
Imaging devices	Scanning machine
Medical equipment	Patient monitor, hemodialysis machine
In Vitro diagnostic devices	Glucometer
Personal protective equipment	Mask, gown
Surgical and Laboratory equipment	

Table 1: Type of medical devices as per WHO (WHO, 2023).

Nowadays, medical devices are widely used for treating diseases as well as to enhance the quality of life of patients (Gagliardi *et al.*, 2018). However, there is always a risk in using medical devices. The manufacturers and regulatory authorities have to continuously monitor the medical devices to ensure safety (Altayyar, 2020).

Materiovigilance is the adverse event reporting of medical devices. It involves identification, monitoring and prevention of adverse events due to medical devices to ensure patient safety. Patient safety is an integral part of the pharmaceutical industry. In the current world of advanced technology, the use of medical devices has significantly increased in diagnosis, treatment and for life support. Materiovigilance plays an important role in recalling defective devices and enhancing the safety of medical devices (Sapkota *et al.*, 2023).

The International Medical Device Regulators Forum (IMRDF) was established for the implementation and harmonization of materiovigilance activities globally in 2011. In different countries, medical devices are monitored and controlled by different rules and regulations by different regulatory authorities. A few of the countries and their respective regulatory authorities monitoring the medical devices are listed below in **Figure 1** (Sapkota *et al.*, 2023).

USA	• Center for Devices and Radiological Health (CDRH) of US FDA
United Kingdom	• Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	• Therapeutic Goods Administration (TGA)
Canada	• Health Canada
Ireland	• Health Products Regulatory Authority (HPRA)
China	• China Food and Drug Administration (CFDA)
India	• Central Drugs Standard Control Organization (CDSCO)

Figure 1: List of regulatory authorities monitoring medical devices (Sapkota et al., 2023).

1.1 Significance of the study:

The patients might experience adverse events from medical devices after months or years of implantation of the device. Thus, post marketing surveillance or monitoring of medical devices is important to collect data about medical device adverse events (MDAE). This safety data would help manufacturers and regulators to take necessary actions and avoid any future recurrence of the same adverse events (Gagliardi *et al.*, 2018). The adverse events due to medical devices can be reported to the concerned authorities by the patients, consumers, technicians and healthcare professionals (Yoon *et al.*, 2019).

Globally, there were several incidences of adverse reactions and recalls of medical devices. As per the literature, millions of patients suffered injuries due to medical devices and thousands died (Souza *et al.*, 2021). In the United States, there were multiple reports of deaths and lymphoma in patients who used breast implants from the late 1990s to 2000s (Abi-Rafeh *et al.*, 2019). Between 2018 and 2022, the number of medical devices recalled in the United States was 13,623 and the majority of recalled devices were cardiovascular devices and implants (Mooghali *et al.*, 2023). Recently, in 2022 and 2023, the US Food and Drug Administration issued recall notifications for various products including ‘Philips Respironics BiPAP’ due to possible chemical contamination causing hypersensitivity and headache, ‘Integra CereLink intracranial pressure monitor’ due to

incorrect readings causing patient injury and death, 'Walnut wearable smart thermometers' due to burn injuries and skin reactions and 'Abbott's glucose monitoring system' due to overheating and spark (US Food and Drug Administration, 2023b). In Canada, from December 2019 to February 2023, 5741 medical device incidents were reported and most of the reports were from devices used in cardiovascular, urology and anesthesiology (Health Canada, 2023). In 2019, there were reports of stent dislodgement for the 'Cordis Palmaz Genesis stent' from various countries including the United States, China, France, Netherlands and Brazil (Central Drugs Standard Control Organization, 2023).

In India in 2010, the hip implants released metallic particles into the bloodstream causing adverse reactions to the patients which were eventually recalled. In India, there were also reports of death and burn injuries of infants due to overheating of incubators. As there was a rise in adverse reactions of medical devices, the Materiovigilance Programme (MvPI) was initiated in India in 2015 (Joshi *et al.*, 2021; Shukla *et al.*, 2020). In 2022, a medical device alert was published in India for 'MitraClip', a heart valve repair device due to its possible malfunctioning and a recall notification was published for 'Cordis Palmaz Genesis stent' (Central Drugs Standard Control Organization, 2023).

The above-mentioned data suggests that there is a need for proper monitoring of adverse events due to medical devices for the safety of the patients. Thus, it is necessary that the healthcare professionals are aware of materiovigilance and its regulations. Multiple studies have already assessed the knowledge, attitude and practice of pharmacovigilance among healthcare professionals, however only very few published studies were available for materiovigilance with a limited number of participants. In India, the Materiovigilance Program was established in 2015. Thus, it is significant to carry out a knowledge, attitude and practice assessment about materiovigilance among doctors, nurses, pharmacists and dentists in South India after 8 years of implementation of the Materiovigilance Programme in India.

1.2 Research Objectives:

1. To carry out a literature review of articles discussing medical device adverse event (MDAE) reporting and regulations published from 2015.
2. To determine the extent of knowledge, attitude and practice of materiovigilance among healthcare professionals in South India using a questionnaire.

3. To identify the gaps or factors that affect MDAE reporting by healthcare professionals in South India.
4. To analyze the data and provide recommendations for further actions if required.

1.3 Research Questions:

1. What is the extent of knowledge, attitude and practice of Materiovigilance among healthcare professionals in South India?
2. What are the factors affecting adverse event reporting of medical devices by healthcare professionals?
3. What are the actions that can be taken to increase knowledge and practice of Materiovigilance?

1.4 Thesis Layout:

This study paper commences with an introduction chapter discussing the significance and objectives of this study. The main purposes of this study were to evaluate the extent of awareness, and to determine the level of attitude and practice of materiovigilance among healthcare professionals working in South India. The next chapter is literature review which discusses relevant published literature articles. The literature review chapter includes discussions from peer reviewed review articles, research articles, books and relevant government and regulatory authority websites. Further, the research methodology chapter explains the primary research methodology and its design.

In this study, a quantitative survey-based method was used to collect primary data. The questionnaire was prepared in Google Forms and shared with doctors, nurses, dentists and pharmacists. The questionnaire had five sections. Section one included questions about age, profession and work experience. Section two included closed-ended, multiple choice and scenario-based questions to assess the knowledge. Section three included Likert scale questions to assess the attitude and section four included questions to evaluate the practice of materiovigilance. Section five included a rating scale and an open-ended question to provide recommendations and opinions for further improvement of materiovigilance in India.

Chapter 4 of this thesis is findings and analysis. In this chapter, the obtained primary research data and literature review were discussed and analyzed using statistical methods. The last chapter is the

conclusion and recommendations in which the summary and further recommendations are mentioned.

CHAPTER 2: LITERATURE REVIEW

2.1 Medical devices and its classification:

Medical devices are currently used for the diagnosis, prevention and treatment of diseases. Medical devices can be metered dose inhalers to life-saving pacemakers. It can be external devices or internal devices, instruments, apparatus, implants and combination products. Combination products are a combination of drugs and devices (Sapkota *et al.*, 2023; Deshwal *et al.*, 2020). Few examples are stents, incubators, prosthetic devices, syringes, orthopedic implants, heart valves, bone cement, catheters and intrauterine contraceptive devices (Hoda *et al.*, 2020).

2.1.1 Classification of medical devices:

Depending on the level of risk, medical devices are divided into different categories by various countries. However, in India, medical devices are categorized based on the level of risk and level of health hazard. Based on the level of risk medical devices are classified into class A (low risk), class B (low-moderate risk), class C (moderate to high risk) and class D (high risk). Based on the level of hazard medical devices are classified as type 1 (high level of hazard including death), type 2 (temporary issues) and type 3 (does not cause health consequences) (Joshi *et al.*, 2021).

In Europe, medical devices are classified into 4 classes namely, class I (low risk), class II (low-medium risk), class III (medium- high risk) and class IV (high risk). As per regulations in Australia, medical devices are classified into class I (low risk), class II a (low medium risk), class II b (medium-high risk) and class III (high risk). In the United States, medical devices are divided into 3 categories namely, devices requiring general controls, specific and general controls and devices requiring pre-marketing approval (Joshi *et al.*, 2021).

2.2 Significance of adverse event monitoring of medical devices:

The use of medical devices has increased significantly. However, like drugs medical devices can cause adverse events. The use of medical devices is accompanied by certain risk factors (Hoda *et al.*, 2020). The most common reasons for adverse events of medical devices are defects in manufacturing, improper maintenance, storage errors, lack of proper training and use in unapproved indications (Sapkota *et al.*, 2023). There were reports that medical devices which were unsafe and faulty were marketed and used in various countries around the globe. These medical devices have caused multiple injuries and fatalities (Joshi *et al.*, 2021). Most of the medical devices

have certain levels of risk which could not be identified in the initial stages of development or during clinical studies. Thus, there is a need for post marketed study of medical devices (Indian Pharmacopoeia Commission, 2017b).

2.2.1 Medical device adverse event across the globe:

Adverse events were prevalent among incubators, pacemakers and implants. In 2009 and 2010, the hip implants of Johnson and Johnson were recalled globally as the implants released metals like chromium and cobalt into the bloodstream of patients causing adverse reactions. One of the patients with this hip implant experienced visual problems, cardiac issues and walking difficulties (Deshwal *et al.*, 2020; Joshi *et al.*, 2021).

In 2014, a patient was implanted with a spinal cord stimulator, but the implant failed, and the patient fell down. As per the reports, around 500 patients had fatalities due to spinal cord stimulators (Joshi *et al.*, 2021). In the United States, the failure of an implantable defibrillator to work caused the death of a 27-year-old female patient. In 2016, the US Food and Drug Administration (US FDA) recalled implantable cardioverter defibrillators. In 2017, four infants died in India in an incubator and multiple other cases of incubator injuries and fatalities were reported in India (Joshi *et al.*, 2021). By the year of 2017, 249 serious adverse events of urogynaecological mesh were reported to the Therapeutic Goods Administration (TGA) in Australia (Craig *et al.*, 2019).

Another case of medical device adverse event discussed in the literature is of cardiac pacemakers. The patients who used pacemakers of 'Azure, Astra, Percepta, Serena and Solar' experienced adverse events like dizziness, shortness of breath and even death (Deshwal *et al.*, 2020).

2.2.2 Medical device adverse events in dental practice:

Multiple devices are used in the practice of dentistry. A few examples of devices used in dentistry are endodontic files, orthodontic devices, dental implants, prosthetics and dental bur. These devices have caused many adverse events including injuries to deaths. Even though these devices are commonly used by dentists, these devices have risk factors (Hebballi *et al.*, 2015).

A journal article discussed about adverse events in dentistry and mentioned about device related serious infections, allergy to orthodontic brackets and failure of implants (Kalenderian *et al.*, 2021). Failure of dental implants has also caused pain, hard tissue injury and infection in various patients (Walji *et al.*, 2020).

There were reports of adverse reactions and events due to orthodontic sequential aligners. The patients experienced dental issues like chipping of teeth, loss of teeth, mouth ulcers and other issues like nausea, headache, fever, allergic reactions, cardiac issues, chest pain and candidiasis. There were even a few reports of oral cancer (Thavarajah and Thennukonda, 2015). Recently, clear aligners and retainers are popular. However, there are reports of soreness of the tongue, swelling of lips, blisters, ulcers and breathing difficulty in few patients (Yazdi *et al.*, 2023). Dental prosthetic devices are also being used and few patients experienced stomatitis, burning mouth syndrome, delayed hypersensitivity reactions and allergic reactions to metal alloys (Alnazzawi, 2017).

A review article discussed about adverse events caused by oral appliance therapy (OAT) in patients from various parts of the world like Europe, Asia, New Zealand, Australia and North America. The side effects discussed in the article include pain, tongue irritation, gingival irritation, abnormal salivation, allergic reaction, suffocation and breathing difficulty (Sheats *et al.*, 2017).

In March 2023, the US FDA published a notification regarding the safety concerns of palatal expanders like anterior growth guidance appliances and anterior remodeling appliances among adults. These devices caused issues like dislocation of teeth, flared teeth, erosion of teeth and loss of teeth (US Food and Drug Administration, 2023a).

In addition to direct adverse events caused by medical devices, the errors of medical devices might cause wrong diagnoses and interventions causing harm to the patient. Hence, there is a significant requirement for proper post marketed monitoring and knowledge about adverse events due to medical devices (Indian Pharmacopoeia Commission, 2017b).

2.2.3 Responses to medical device adverse events by regulatory authorities and manufacturers:

In 2000, 'Inter OP acetabular cups' were recalled due to complaints of pain and inflammation post-surgery in patients due to endotoxin contamination of the implant (Wyss, 2019). The patients who used 'Essure' a stainless steel-nickel titanium coil for female sterilization experienced allergic reactions to metal, pain and bowel injury. Around 5000 adverse events were reported to FDA regarding 'Essure'. As directed by the FDA, the manufacturer had to conduct extended studies to evaluate benefit and risk. From the year of 2008 to 2011, there were 2874 adverse event reports of transvaginal mesh including pain and site infection and FDA issued a notice (Carey *et al.*, 2017).

Between 2011 and 2021, 315 implants of osteosynthesis and 286 joint replacement implants were recalled from Canada, China, Australia and the United States (Wang *et al.*, 2022). In 2012, 'Zimmer Durom' hip replacements were recalled by the company itself due to increased ion release and improper functioning. In 2015, 'Zimmer persona' metal tibia plate was recalled due to reports of radiolucent lines (Wyss, 2019). In 2020, Covid-19 testing kits were recalled in India due to non-performance and in 2021, Covid-19 testing kits were recalled in the United States due to false positive tests (Sapkota *et al.*, 2023).

2.3 Global regulations for medical devices:

Around the world medical devices are regulated by different regulatory authorities. In the US, medical devices are regulated by the US Food and Drug Administration (USFDA) and the manufacturers have to get prior approval from FDA for marketing the device in the United States. As per 21 Code of Federal Regulations (CFR) part 803, manufacturers, importers, healthcare professionals, patients and consumers can report adverse events and product quality issues using an electronic -medical device reporting form (Joshi *et al.*, 2021).

In Europe, medical devices are regulated based on guidelines of the European Union and directives of the European Commission. There are different directives for implanted devices, diagnostic devices and additional devices. In Europe, medical device adverse events (MDAE) should be reported by manufacturers or healthcare professionals to the National Competent Authority (NCA) using a manufacturer incident reporting form. Serious cases have to be reported to the NCA within two calendar days and non-serious cases within 30 calendar days (Joshi *et al.*, 2021).

In Australia, Therapeutic Goods Act regulated devices since 1989. In 2002, Australia became part of the Global Harmonization Task Force (GHTF). Manufacturers and sponsors can report adverse events using online reporting forms. Fatal and serious cases must be reported within ten calendar days while non-serious cases within 30 calendar days. Events requiring immediate action should be reported within 48 hours (Joshi *et al.*, 2021).

There are specific regulations and monitoring for medical devices in other countries like Canada, China and Japan (Joshi *et al.*, 2021).

2.4 Medical devices regulations in India:

Traditionally, in India medical devices were regulated based on the Drugs and Cosmetics Act 1940 and Rules 1945. Previously, there was no system to monitor or analyze adverse events of medical devices in India. In the year of 2015, the Materiovigilance Programme of India (MvPI) was implemented under the Indian pharmacopeial commission. Later in 2017, the Medical Devices rule was implemented in India (Deshwal *et al.*, 2020; Joshi *et al.*, 2021).

2.4.1 Materiovigilance Programme of India and its significance:

The hip implants of Johnson and Johnson were recalled due to adverse events from 2009 by the regulatory authorities of Australia, the US and the United Kingdom and even the company itself recalled the product globally by 2010. However, the Indian regulatory system issued the alert in November 2013 causing trouble to patients in India. If there was a proper monitoring of medical devices in India from the initial stages this could have been avoided (Deshwal *et al.*, 2020).

The medical device adverse events of blood poisoning due to hip implants and fatal burn injuries of infants led to the implementation of the Materiovigilance Programme in India. The Materiovigilance Programme of India involves the identification, collection and reporting of adverse effects of medical devices and the regulatory authorities would respond by recalling the device or by taking field safety corrective actions. The Materiovigilance Programme of India was implemented in 2015 (Joshi *et al.*, 2021). The National Coordination Center for this program is the Indian Pharmacopoeia Commission (IPC) and National Collaboration Center is Sree Chitra Tirunal Institute for Medical Sciences and Technology Thiruvananthapuram (SCTIMST). The national regulator of the Materiovigilance Programme is Central Drugs Standards Control Organization (CDSCO), New Delhi. The primary objective of the Materiovigilance Programme is to improve the safety of patients as well as healthcare professionals by avoiding medical device adverse events (Indian Pharmacopoeia Commission, 2017b). The mission of the program is to ensure better risk benefit for medical devices (Indian Pharmacopoeia Commission, 2017a). The main aims of this program are to monitor adverse events of medical devices, provide awareness to healthcare professionals, consumers and other stakeholders about adverse events due to medical devices and to enhance the safety of patients by preventing recurrence of the adverse events by interventions like recalls or alerts (Hoda *et al.*, 2020).

MvPI works in coordination with other organizations and institutes like World Health Organization (WHO), IPC, CDSCO, SCTIMST and the National Health System Resource Center (Indian

Pharmacopoeia Commission, 2017a). MvPI also works in harmony with GHTF (Joshi *et al.*, 2021). Currently, India has 293 medical device adverse event monitoring centers of which 148 centers are in South India (Indian Pharmacopoeia Commission, 2017b).

2.4.2 Medical device adverse event reporting in India:

The adverse events of medical devices are classified into three categories based on its severity, namely death, serious injury, and near-miss event (Indian Pharmacopoeia Commission, 2017b).

2.4.2.1 Reporters and reporting form:

In India, adverse events related to medical devices can be reported by manufacturers, biomedical engineers, hospital technology staff, doctors, nurses, pharmacists, patients, dentists and other healthcare professionals using medical device adverse event (MDAE) reporting forms. Both serious and non-serious cases can be reported (Indian Pharmacopoeia Commission, 2017b). The MDAE reporting form is available in English and one local language. Two different forms are available for consumers and healthcare professionals. In the MDAE form the reporter needs to fill in general information about the patient, details of the device and details of adverse events (Hoda *et al.*, 2020; Indian Pharmacopoeia Commission, 2017c).

2.4.2.2 Adverse event monitoring process:

The healthcare professionals or patients or any stakeholder who identifies a MDAE can report to the concerned authority using different reporting methods. The reporters could fill in the form and could directly submit it to an adverse event monitoring center (AMC) or medical device adverse event monitoring center (MDMC). The reporters could also use the helpline number of IPC to report adverse events. The reporters could send an email to IPC or send directly using the postal service. Recently 'PVPI mobile app' is also available to report the adverse events (Indian Pharmacopoeia Commission, 2017c). The reporting process is explained in **Figure 2**. Serious events should be reported to the IPC within 15 calendar days (Indian Pharmacopoeia Commission, 2017b).

The reported cases will be evaluated by the monitoring centers and if required follow-up would be performed. Further, a monthly report would be submitted to the National coordinating center (NCC). NCC studies the report and identifies signals. The findings and conclusions from the NCC are submitted to the CDSCO for further regulatory actions (Hoda *et al.*, 2020). The field safety corrective action (FSCA) is used to notify regulators and other stakeholders regarding recalls or

corrective actions (Indian Pharmacopoeia Commission, 2017b). In the last 8 years in India, the CDSCO has issued 18 alerts for medical devices (**Figure 3**) (Central Drugs Standard Control Organization, 2023).

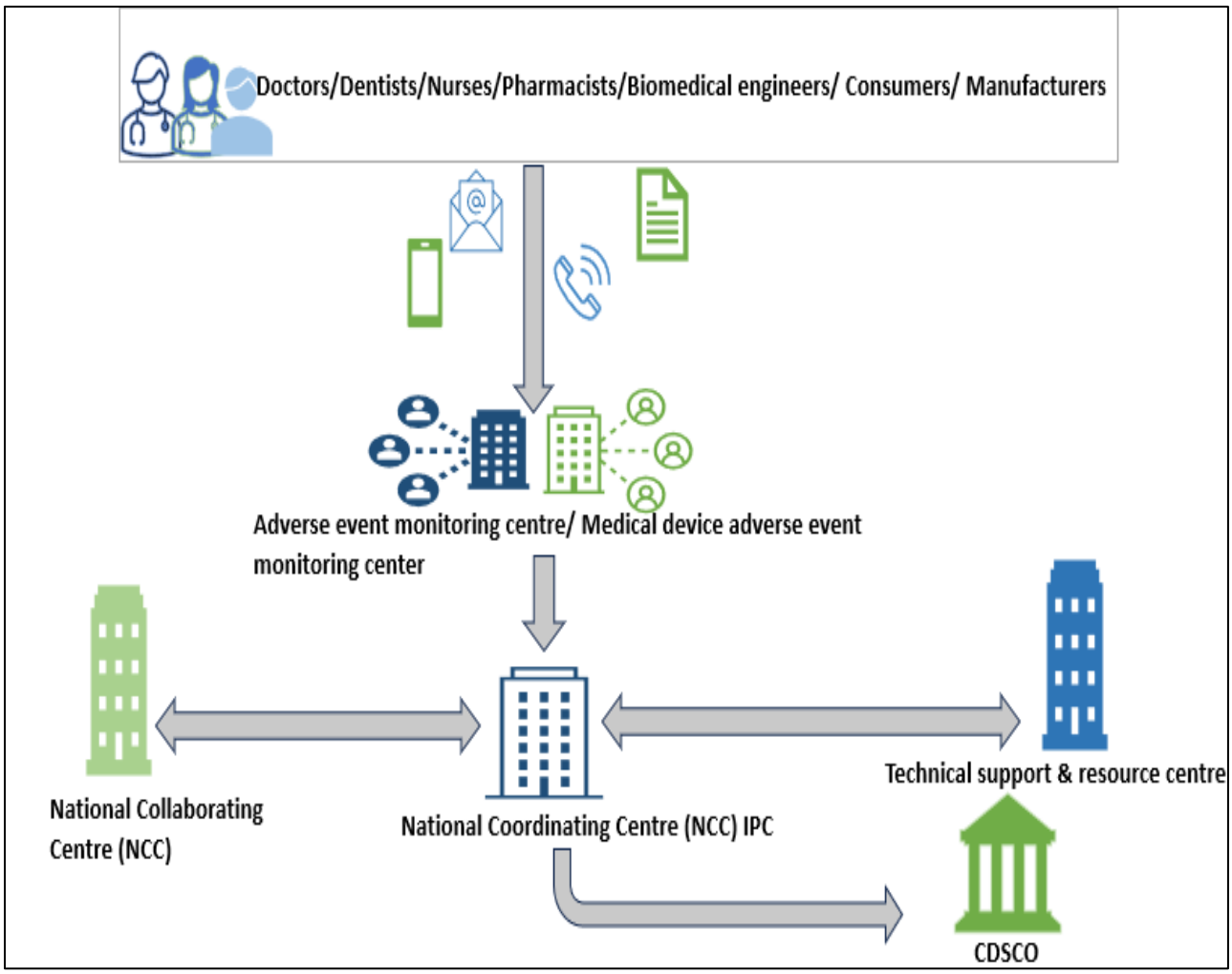

Figure 2 Medical device adverse event reporting process in India (created by author).

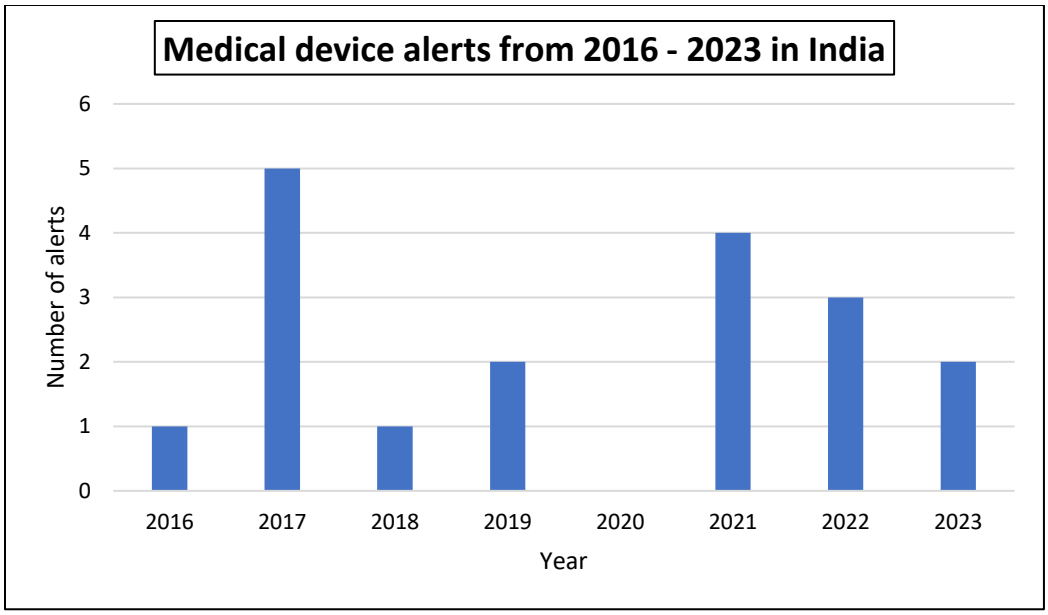

Figure 3: Medical device alerts 2016-2023 (created by author, data taken from (Central Drugs Standard Control Organization, 2023).

2.5 Role of healthcare professionals in the monitoring of medical devices:

There could be adverse events that could not be identified during the device development stage or during clinical trials. So similar to drugs, spontaneous adverse event reporting by healthcare professionals plays a significant role in ensuring patient safety (Sapkota *et al.*, 2023). The healthcare professionals can report adverse events related to cardiac devices and stents voluntarily and can communicate the relevant information to the patients (Kalaiselvan *et al.*, 2020). Adverse events due to orthopedic implants are very common and reporting of adverse events is mandatory for manufacturers whereas it is voluntary for healthcare professionals. As per reports, only 2.4 percent of adverse events were only reported in India about orthopedic implants and the author suggested for a more sophisticated reporting system to increase reporting (V *et al.*, 2023).

In the year 2000, an acetabular cup called 'Inter-Op' manufactured by Sulzer Orthopedics was used in hip implant surgeries. However, a few days post-surgery, the patients experienced pain, swelling and redness at the site of the implant. This also led to revision. The surgeon identified these unexpected events and notified the manufacturer. The company further studied the device in detail and identified endotoxin contamination in the device. The company recalled the devices. It was the surgeon who identified the adverse events first and notified the manufacturer in time. Thus ensuring patient safety (Wyss, 2019).

In Australia, 249 cases of urogynaecological mesh were reported to the Therapeutic Goods Administration (TGA) by 2017. However, there were in total 2400 women experienced issues with the device during the same time which were not reported to the TGA. This shows that there was a lack of reporting from the specialists who implanted the mesh and from doctors who treated the patients for their adverse events. Thus, doctors and healthcare professionals must have knowledge and awareness about medical device adverse events and its reporting process (Craig *et al.*, 2019).

A descriptive qualitative study was carried out among specialists in cardiology and orthopedics practicing in different parts of Canada. The paper discusses the various factors influencing reporting of medical device adverse events. As per the doctors who participated in the study, it was unnecessary to report the adverse events of medical devices as it was expected in their practice and they themselves solved the issue or switched to another device available in the market. The doctors also mentioned the lack of a proper system or process in their work environment. The author concluded that educating and training physicians would not be effective without a systematic process in place to monitor adverse events due to medical devices. However, this study result is based on the opinions of 22 participants in a single geography only thus it cannot be generalized (Gagliardi *et al.*, 2018).

In 2018, an article discussed about the level of knowledge about medical device adverse event reporting among nurses working in intensive care units (ICU) in a hospital in Saudi Arabia. The response rate of the study was only 59 percent, and more than 60 percent of study participants were not aware of the reporting system in the country. The author concluded that there is a need for nurses to be aware of the national reporting process of the country (Alsohime *et al.*, 2019).

A study was carried out among nurses working in a hospital in South India to evaluate knowledge, attitude and practice of materiovigilance. The study was conducted using a self-administered questionnaire which was validated. The results showed that the nurses had sufficient knowledge and a positive attitude towards materiovigilance. The practice of materiovigilance was less because of concerns of legal issues and lack of confidence in filling in the form correctly. This study was conducted in a hospital which was also a medical device adverse event monitoring center. Thus, the results of this study cannot be generalized (Sivagourounadin *et al.*, 2022). Another study was carried out among nurses working in a hospital in Kolkata using questionnaires in English and two local languages. The results showed a high response rate. The participants had adequate knowledge

and had a positive attitude towards materiovigilance. The author identified a gap between knowledge and actual practice of materiovigilance. The author suggested the use of posters and newsletters in nursing stations to improve the practice of materiovigilance (Manna *et al.*, 2023).

The knowledge, attitude and practice of materiovigilance among dentists working in both public and private sectors in Senegal were studied. A simple random sampling process was used to include participants in the study. In this study, allergy was identified as the most common adverse event due to dental medical devices. The study showed that around 53 percent of dentists had encountered adverse events in their practice of dentistry and the attitude was to stop using the device. However, around 86 percent of dentists did not report the events. The study also identified that 88.5 percent of participants were not trained in materiovigilance (Aida *et al.*, 2016).

In 2021, a study was conducted among surgeons in North India using a Google Form questionnaire to assess knowledge, attitude and practice of materiovigilance. The study revealed a lack of adequate knowledge and practice of materiovigilance among surgeons. However, the participants of the study showed a positive attitude towards materiovigilance. The study included only a limited number of participants (Panchal *et al.*, 2022). In a study conducted in a tertiary care hospital, the doctors of different departments like medical, surgical and diagnostic had knowledge about materiovigilance but lacked knowledge about the adverse event reporting process. (Tantia *et al.*, 2023). The studies conducted among various healthcare professionals like teaching staff in medical colleges, residents and doctors showed good attitudes towards medical device adverse event reporting and poor practice and knowledge of materiovigilance (Meher *et al.*, 2022; T *et al.*, 2023). A study revealed moderate knowledge and poor practice of materiovigilance among doctors, nurses and technicians (Srinivas *et al.*, 2022).

2.6 Global under-reporting of medical device adverse events:

As discussed in a review article, the main reasons for underreporting of medical device adverse events (MDAE) in Australia are lack of awareness about the process, lack of time, complex reporting process and fear of further complications. Another reason is that the problem might be resolved by the professional, so they did not want to report the event. In some cases, the professionals did not identify that the event was related to a medical device (Craig *et al.*, 2019).

An article with a review of 30 published articles discussed the main reasons for under-reporting and strategies to improve reporting among healthcare professionals. The studies included in the

review were published in the US, United Kingdom, Australia, Canada, Korea, China, Pakistan, France, Italy and the Netherlands thus, the article has opinions from healthcare professionals across the globe. Based on the review, the author concluded that the main factors affecting reporting are lack of awareness, lack of support from the concerned organizations, time constraints, fear of punishments or blame and legal complications (Polisena *et al.*, 2015).

A study was carried out among regulatory members of Asia Pacific using a scenario-based questionnaire. The study concluded that there are differences in the perspectives while identifying medical device adverse events due to lack of knowledge. As per the author, the perspective difference is one of the major reasons for under-reporting of MDAE. Thus, the author recommended for more training and education for the professionals working in healthcare (Yoon *et al.*, 2019).

According to a study conducted among physicians working in Canada, the main reasons for under-reporting include lack of proper systems in their hospitals, lack of feedback, lack of incentives and non-identification of adverse events. As per the participants it was not their responsibility to report the adverse events and they did not follow up with the patients post-surgery (Gagliardi *et al.*, 2018).

2.7 Recommendations for improving safety of medical devices:

To avoid adverse events or tragedies due to medical devices, hospitals and institutions must procure standard and qualified medical devices. There should be processes in place to avoid the procurement of unqualified and substandard devices. Another approach is to encourage and train all medical workers to report adverse events within the timeline to avoid future tragedies or the recurrence of adverse events. The patients can be followed up regularly post-surgery by the institutions to ensure patient safety. The literature also suggests the need for premarket safety assessment studies. The studies also emphasize the need for an easily accessible adverse event reporting system (Wang *et al.*, 2022).

Few reports had revealed that the fear of legal issues is a major reason for under-reporting. In order to overcome these issues certain countries have adopted the feature of anonymous reporting. In the United States anonymous reporting method is used in ‘MedSun (medical product safety network)’ by the US FDA. In Denmark, as per the Danish Act 2004 on patient safety, the reporter could not be penalized, and the details of the reporter will be kept anonymized. This process has increased

the reporting by 80 percent in Denmark within two years of the implementation of the act (Alsohime *et al.*, 2019).

In Australia, a pilot program called the 'InSite Programme' was implemented in two facilities to educate and assess knowledge of healthcare professionals about adverse event reporting. The program showed positive results and when training was not further continued the number of reports decreased which indicated the need for continued education among healthcare professionals (Craig *et al.*, 2019).

2.8 Conclusion:

After a comprehensive review of literature articles, government websites and regulations related to medical devices and materiovigilance, it was identified that there is a need for further studies in the area of materiovigilance in India. As per the literature, the use of medical devices was increasing day by day in healthcare as well as in dentistry. It was evident from the literature and regulatory websites that medical devices have high risk factors and have caused multiple adverse events including death. Thus, it was necessary to monitor and identify adverse events caused by medical devices. Different countries have different regulatory authorities to monitor medical devices.

Healthcare professionals play a major role in ensuring patient safety while using medical devices and they have to identify the adverse events caused by medical devices. Multiple studies and incidences across the globe indicated that there is a lack of awareness about materiovigilance and a lack of reporting of medical device adverse events. Few studies were carried out to assess the knowledge, practice and attitude among doctors and nurses with a limited number of participants working in a single institution. Most of the studies revealed less than below average to adequate knowledge, positive attitude and a lack of practice of materiovigilance. Based on studies conducted in Australia, Canada and Asia-Pacific few reasons for the lack of practice of materiovigilance were identified.

However, most of these studies were carried out in a single hospital or an institution with a limited number of participants. The group of participants included in these studies were mostly medical doctors and nurses. The level of knowledge, attitude and practice of Materiovigilance among dentists and pharmacists were not deeply studied. It is significant to study knowledge, attitude and practice of materiovigilance among doctors, nurses, dentists and pharmacists working in different

sectors and parts of South India. Thus, obtaining broader data about the level of awareness and practice of materiovigilance in India. The study would also collect opinions and recommendations from the healthcare professionals which might include better suggestions to improve the Materiovigilance program of India.

CHAPTER 3: RESEARCH METHODOLOGY

This study was carried out using a non-interventional and cross-sectional quantitative research methodology using a survey. This chapter discusses the conceptual framework, research philosophy, research approach and research strategies used in this study. The details of participants, exclusion-inclusion criteria, data collection and conduct of study are explained in detail in the below sections. The methodology used for data analysis is also explained. This study was conducted among registered doctors, nurses, dentists and pharmacists in South India.

3.1 Conceptual framework:

In this study, the level of knowledge and attitude of healthcare professionals towards materiovigilance was studied. The relation between knowledge and practice of materiovigilance was also discussed. Using the data from the literature and the opinions from the respondents, the gaps or factors affecting the knowledge, practice and attitude of healthcare professionals in South India towards adverse event reporting of medical devices were identified. Based on the collected data, recommendations for further improvement were suggested. **Figure 4** represents the conceptual framework of this study.

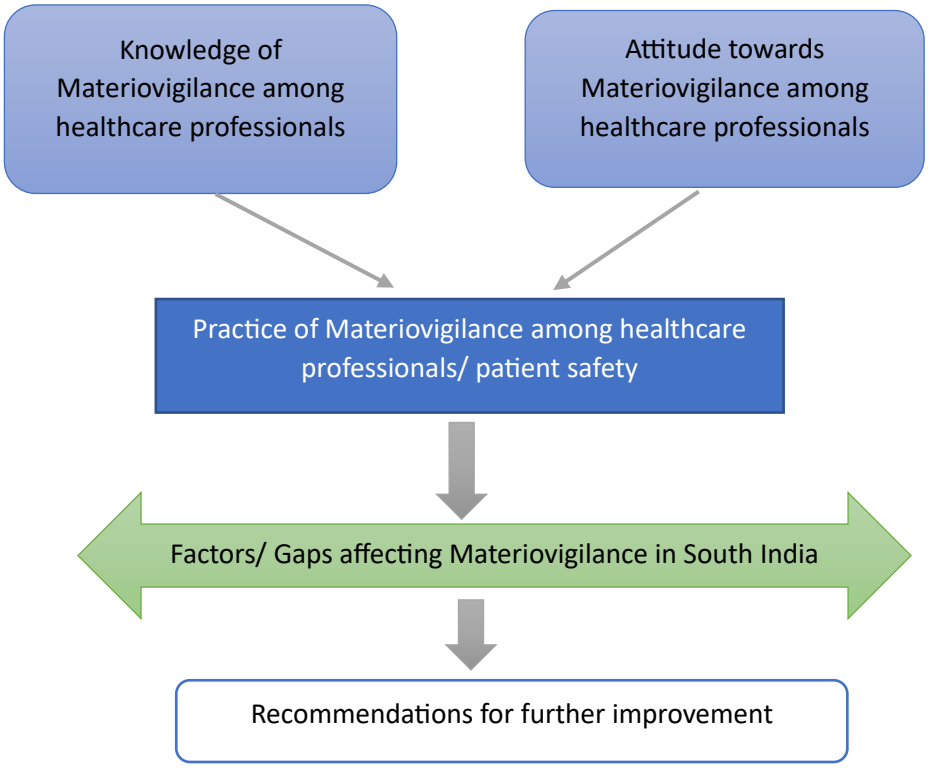

Figure 4: Conceptual framework (created by author).

3.2. Research Philosophy:

The main purpose of research is to study and gain in-depth knowledge about a particular area. The researchers have certain assumptions and plans to conduct the research (Saunders *et al.*, 2006). The philosophical aim of this study is to gain in-depth knowledge about materiovigilance in India. This study was carried out using a quantitative research method using a survey.

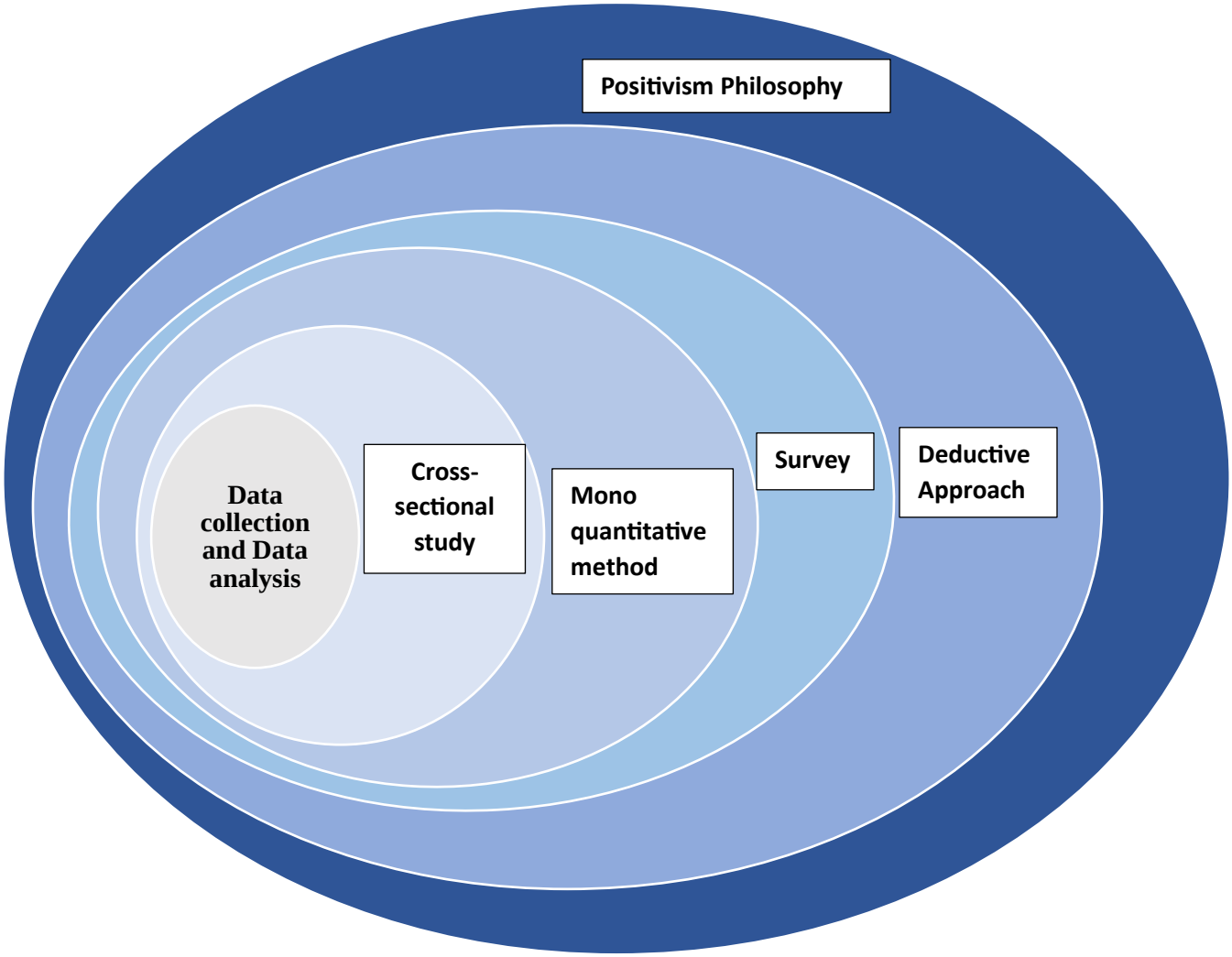

Figure 5: Representation of Research Philosophy using Research Onion (created by the author, data obtained from (Saunders et al., 2006)).

This study involved collecting data during a specific time period from 10 July 2023 to 10 August 2023 among different healthcare professionals, thus it was a cross-sectional study. The strategy used in this study was the quantitative survey method. A survey was conducted among the participants using multiple closed-ended questions and a few open-ended questions. According to literature articles, the majority of knowledge, attitude and practice studies among healthcare professionals were quantitative using self-administered questionaries while only two studies were conducted using the qualitative method of interview (Saleh *et al.*, 2016). The research philosophy for this study is represented in **Figure 5**.

The study was a quantitative survey using a structured questionnaire. The conclusions were made based on scientific methods and statistical analysis. The survey also focused on the underlying factors of the results and was determined using open-ended question. Thus, the research philosophy of this study is positivism.

3.3. Research Approach:

A research study involves a theory. The studies might test the theory, or a theory would be developed from the results. The research approach is usually based on how the theory is tested or developed in the study. In this study, a deductive approach was used. The deductive approach involves examining an issue, developing a theory or hypothesis and followed by testing the theory or hypothesis. The results of the study were analyzed, and the theory or hypothesis was confirmed or modified based on the findings of the study (Saunders *et al.*, 2006).

Based on the literature review, a relation was identified between knowledge, attitude and practice of materiovigilance among the participants like doctors, student residents and nurses. In this study, a quantitative questionnaire-based survey was conducted among doctors, nurses, dentists and pharmacists in South India to test these conclusions. Further, based on the results of the survey the conclusions could be confirmed or updated. Thus, this study follows a deductive approach.

3.4. Research Strategy:

The strategy was to evaluate the knowledge, attitude and practice of materiovigilance among healthcare professionals. There are different research strategies to conduct a study like surveys, experiments, interviews and case studies (Saunders *et al.*, 2006). The primary research strategy used in this study was a quantitative method using a survey. The survey used a questionnaire to assess knowledge, attitude and practice of materiovigilance among healthcare professionals

(Meher *et al.*, 2022; Panchal *et al.*, 2022). Healthcare professionals included in this study were doctors, pharmacists, nurses and dentists. The study location was South India. In this study, survey-based data collection was advantageous as it was more feasible to share links to participants in another location, living in different time zones. As the participants were healthcare professionals with busy schedules, the survey-based study was appropriate as they had completed the survey in their spare time. The survey method was more economical and better for descriptive as well as quantitative results.

3.4.1. Study participants

This study evaluated the level of knowledge, attitude and practice (KAP) among healthcare professionals. The participants of this study included health professionals working or worked in South India namely medical doctors, dentists, nurses and pharmacists. A random sampling method was used. The participants were from the private and public sectors and from various parts of South India. The participants for this study were selected based on inclusion and exclusion criteria.

The participants included in the study were registered doctors, nurses, pharmacists and dentists working or worked in South India. The participants who were willing to participate in the study by agreeing to the informed consent form were only included in the study. All other healthcare professionals and undergraduate students studying during the study period were excluded from the study. The participants who were not willing to sign the informed consent form and participate in the study were excluded.

3.4.2. Sample Calculation:

The sample size for this study was calculated using the 'survey monkey sample calculator' (SurveyMonkey, 2023). The population size was assumed to be 2,400,000 (Karan *et al.*, 2021). The confidence interval was 95 % with a margin of error of 6% as the study duration was very short. The estimated number of study participants was 267.

3.4.3. Data Collection:

A self-administered questionnaire was prepared in English based on relevant sources of information such as literature articles and regulations (Tantia *et al.*, 2023). A cover page was prepared with background information on the study and the approximate time taken for completion of the study. These were included in the survey (Saunders *et al.*, 2006). Informed consent was also included along with the survey (Panchal *et al.*, 2022). The survey questionnaire had five parts.

In part 1, the general information/ personal information of the study participants was collected. This included the age group, category of healthcare professional and years of experience (Panchal *et al.*, 2022). This data helped the author to identify the participants as per inclusion criteria and to classify the respondents as doctors, nurses, pharmacists and dentists.

In part 2, a knowledge assessment was carried out. This section included 10 questions. The knowledge assessment included closed-end questions, scenario-based questions, multiple choice questions and a short answer question (Meher *et al.*, 2022; Panchal *et al.*, 2022). The data obtained from this section helped the author to understand the extent of knowledge among different categories of healthcare professionals. The knowledge assessment questions were based mostly on regulatory documents.

In part 3, an assessment of attitude was conducted. This section included two 3-point Likert scale questions and a closed-end question. This section aimed to determine the attitude of healthcare professionals toward Materiovigilance in India (Panchal *et al.*, 2022; Saunders *et al.*, 2006).

In part 4, questions to evaluate the practice of materiovigilance among participants were included. This section included closed-ended questions and one multiple choice question. The questions included awareness of newsletters or actions taken after observing a medical device adverse events. The data from this section helped the author to understand the current practice of materiovigilance among healthcare professionals.

Part 5 discussed the opinions and recommendations for further improvement of the practice of materiovigilance in India. The section included a question to rate the current medical device adverse event reporting system in India with one being the minimum rating and five being the maximum rating. This section also helped the author to find the gaps in the current Materiovigilance program of India. An open-ended question was also included in this section to mention the individual opinions of the participants. These opinions helped the author to obtain an in-depth understanding of actions that could be taken or actions that need to be changed to improve the materiovigilance in India.

The survey questionnaire was prepared using Google Forms. Before commencing the survey, the questionnaire was evaluated by a small number of healthcare professionals and minor changes were suggested. Further, a pilot test survey was conducted. After obtaining ethical approval, the

survey was started on 10 July 2023. The survey link was shared among the maximum number of healthcare professionals in South India using technological platforms like LinkedIn, WhatsApp and Email. The survey was shared among doctors, dentists, nurses and pharmacists. The healthcare professionals in direct contact were requested to share the survey link with other healthcare professionals (Panchal *et al.*, 2022; Tantia *et al.*, 2023). Healthcare professionals working in South India were also identified using LinkedIn and the background of the study was discussed. Further, the author shared the survey link requesting to participate in the study. The author also sent reminder messages to healthcare professionals in direct contact. The survey was closed on 10 August 2023.

3.5. Ethical implications:

In the present study, an introduction was included in the survey to understand the background of the study which was shared with the participants. The survey had two sections to obtain informed consent and voluntary participation in the study. The study required certain personal information of participants like age group and profession however, those did not have any ethical implications. The participants were assured that the confidentiality of the data would be maintained.

A similar peer review study stated that as the study was conducted digitally there were few concerns (Tantia *et al.*, 2023). In this study, in order to avoid issues of duplicate participation, the settings of Google Forms were updated to a single response from one email. An ethical form was prepared and submitted to the ethical committee. Ethics approval was obtained prior to the primary data collection.

3.6. Data visualization and data analysis:

The data collected using Google Forms was visualized using features available in Google forms and the automated features in Google Form presented the results as pie charts and bar charts with numbers and percentages depending on the question type. The data collected in Google Forms were exported to Microsoft Excel for further analysis and visualization.

The data obtained from the personal information section was represented in numbers and percentages. The closed-ended questions in the knowledge assessment section were assessed using the scoring system. A score of 1 was given for the right answer and a score of 0 for the wrong answers (Mustafa *et al.*, 2021). The questions in the knowledge section with multiple correct answers were represented in percentages and numbers. An open-ended question in the knowledge

section to specify medical device recalls or alerts was represented as a table. In the attitude section, the scoring system was used. The first question in the attitude section was framed negatively so score 3 was given for disagree, score 2 for neutral, score 1 for agree and score 0 for blanks. The following two questions were given a score of 3 for agree/yes, 2 for neutral/maybe, 1 for disagree/no and 0 for blanks. The total attitude score was between 0 to 9. A mean attitude score above 5.4 (above 60% of the total score) was considered as positive attitude while a mean attitude score below 5.4 was considered as negative attitude (Manna *et al.*, 2023). In the practice assessment section, the scores were 1 for the right answer and score 0 for the wrong answers or blanks. In question 2 in the practice section, score 3 for yes, score 2 for maybe, score 1 for no and score 0 for blank. The rating question in part 5 was visually presented using a bar graph and analyzed using percentages. The gap in the current process was explained and represented numerically. The suggestions and opinions for further improvement from healthcare professionals were analyzed using a thematic approach using word cloud.

The data obtained in Google Forms was exported to Microsoft Excel and the data was coded using Microsoft Excel. The obtained data was statistically analyzed using IBM SPSS software version 29.0.1.0 (Bepari *et al.*, 2019). Descriptive statistical analysis was carried out using mean, median, percentage and number. The KAP scores among doctors, nurses, pharmacists and dentists were compared using the Kruskal-Wallis test (Sivagourounadin *et al.*, 2022; Mustafa *et al.*, 2021). The data were analyzed using statistical analysis to determine the P-value for the level of knowledge, attitude and practice of materiovigilance (Meher *et al.*, 2022). The KAP score of P value < 0.05 was considered significant (Sivagourounadin *et al.*, 2022). The relationship between knowledge and practice was analyzed statistically using Pearson correlation coefficient (Adu-Gyamfi *et al.*, 2022); (Hardeep *et al.*, 2013).

3.7. Conclusion:

Research methodology is an important part of conducting a study. This chapter discussed the overview of the activities performed for conducting this study. The present study was a non-interventional and cross-sectional quantitative study with a positivist research philosophy. This study involves a deductive research approach using a survey. The knowledge, attitude and practice of materiovigilance among healthcare professionals were assessed using a self-administered questionnaire. The data obtained from the survey was analyzed statistically to obtain conclusions.

CHAPTER 4: FINDINGS AND ANALYSIS

The study was conducted using an online survey to evaluate the knowledge, attitude and practice of materiovigilance. The survey was shared with a maximum number of participants. 210 healthcare professionals voluntarily participated and responded to the survey. A large amount of data was obtained. This chapter discusses the findings in a concise form using descriptive analysis, pie charts, bar charts and tables. The results obtained are statistically analyzed in this section. Below sections illustrate the data obtained from the survey.

4.1. ANALYSIS OF DATA:

4.1.1. General information or Personal information:

This section collected general information from the participants. It included age group, category of profession and work experience. This section helped the author to categorize healthcare professionals into doctors, dentists, nurses and pharmacists. The data from this section helped the author to understand the background of professionals who participated in terms of experience.

4.1.1.1. Age group of participants:

Out of 210 participants who responded to the study, the majority of participants were of the age group 21-30 years. 27.1% of participants were of the age group 31- 40 years. The response rate was very low for the age groups 41-50 years and above 50 years. Out of 210 participants, 8 respondents were of the age group 41-50 while only 5 participants were of above 50 years of age. The data is presented in below pie chart (**Figure *6***).

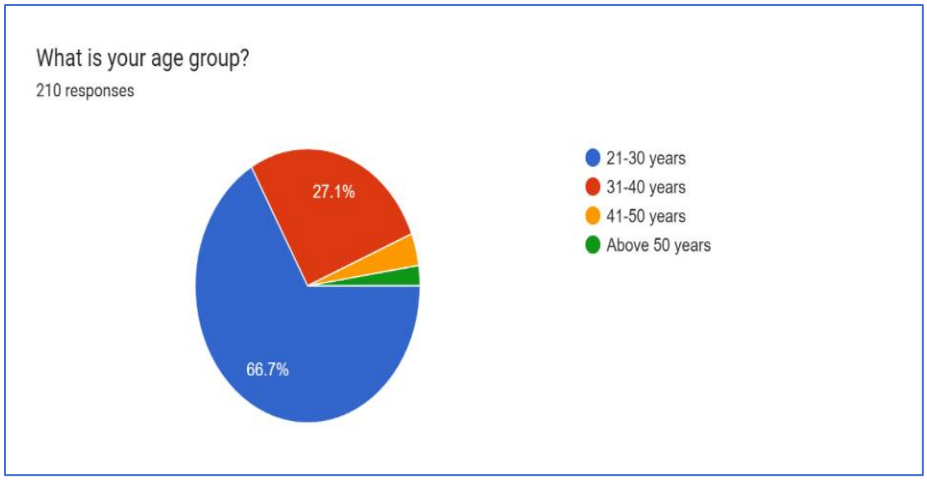

Figure 6: Age group of participants.

4.1.1.2. Category of healthcare professionals:

In total 210 healthcare professionals participated in the survey from various parts of South India. The majority of respondents were pharmacists consisting of 35.7%. 27.15% of respondents were registered dentists. Nurses included 20% of survey participants and only 17.1% were registered doctors. It might be due to their busy schedule that the participation was low from doctors. The below chart (**Figure 7**) represents the percentage distribution of respondents. **Table 2** shows the list of number of doctors, dentists, nurses and pharmacists who participated in this study. All the participants were registered and had sufficient qualifications to take part in the study.

Category of healthcare professionals	Number of respondents
Registered Pharmacist	75
Registered Dentist	57
Registered Nurse	42
Registered Doctor	36

Table 2: Number of healthcare professionals.

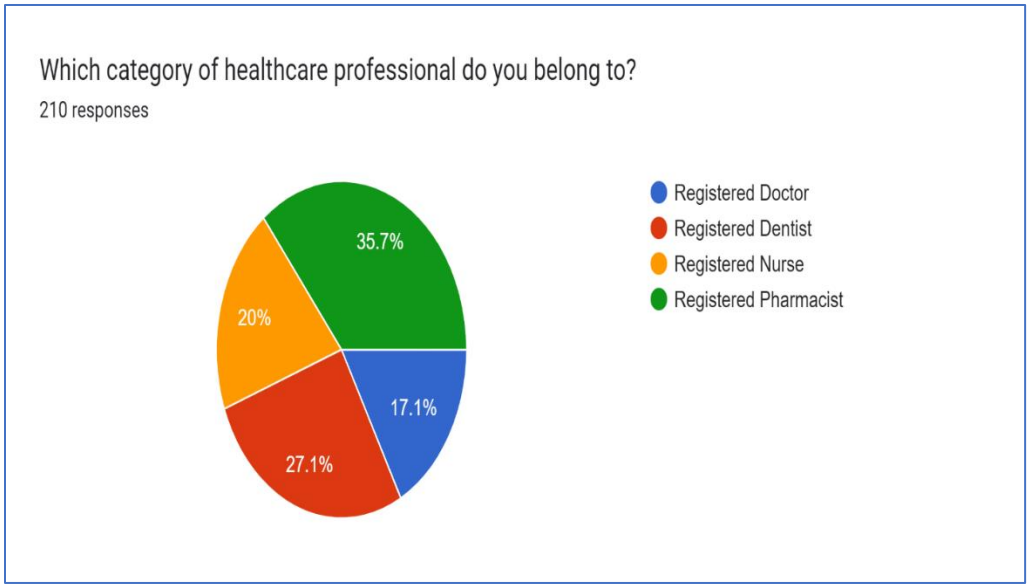

Figure 7: Category of healthcare professionals.

4.1.1.3. Work experience:

In this study, a question was included to understand the level of work experience of the participants. 209 participants out of 210 participants responded to this question. Most of the respondents had work experience of 0-5 years. 17.2% of participants had work experience of 6-10 years. 14 participants had work experience of 11-15 years. However, only 13 participants with work experience above 15 years participated in this study. The data is presented in **Figure 8**.

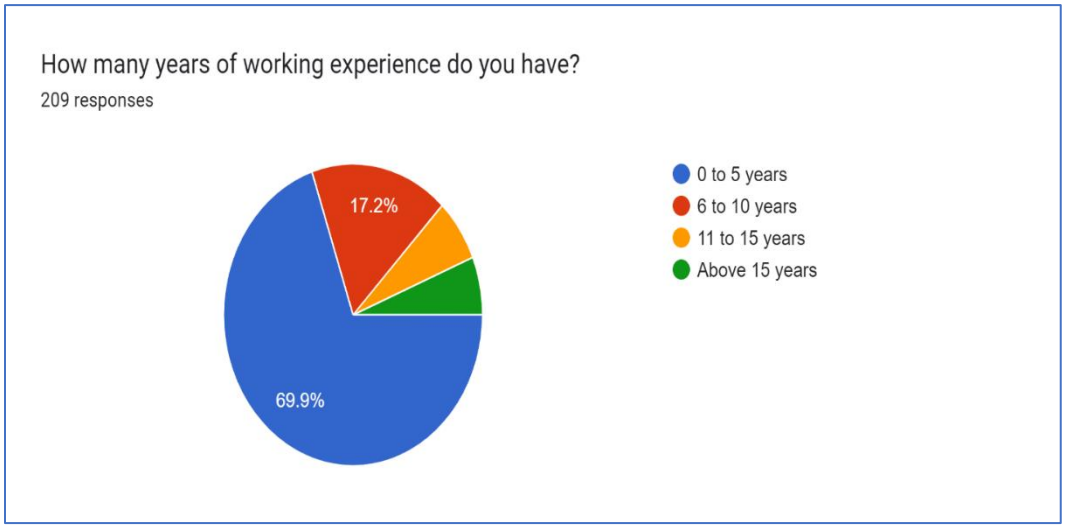

Figure 8: Years of work experience of study participants.

4.1.2. Assessment of Knowledge:

4.1.2.1 Awareness that medical devices can cause adverse events:

Of 210 participants who responded to this study, 95.7% of participants were aware that medical devices could cause adverse events or reactions. Only 4.3% of participants were not aware of medical device adverse events. The below pie chart represents the data (**Figure 9**). This data shows that overall healthcare professionals had knowledge that the medical devices could cause adverse events.

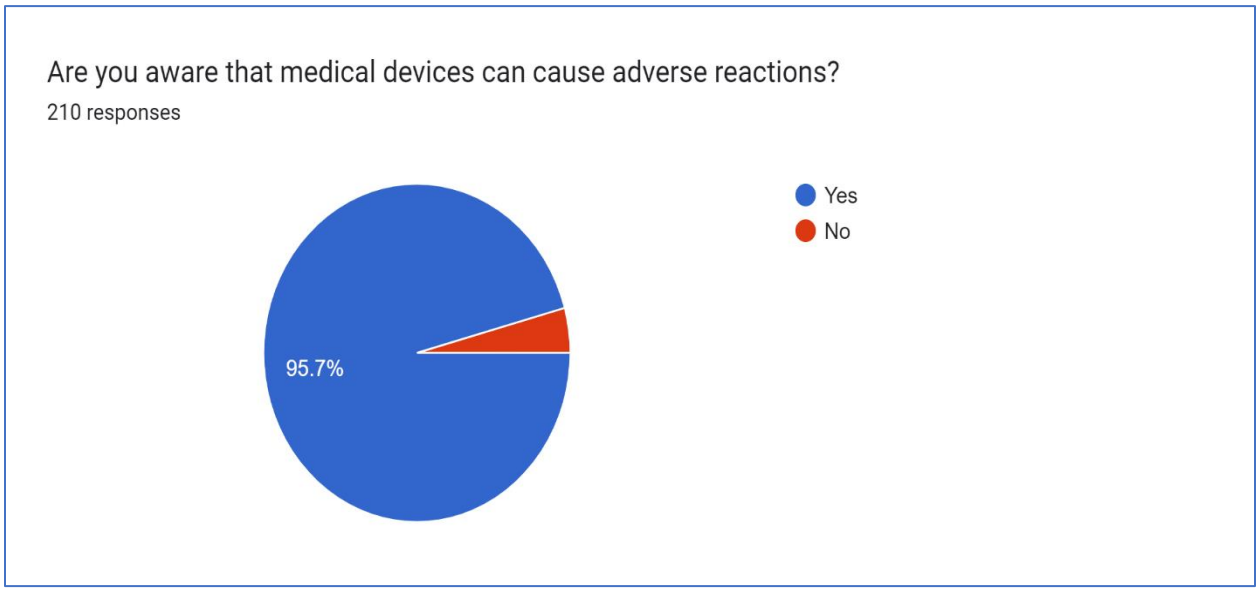

Figure 9: Awareness about medical device adverse events.

Of 36 registered doctors who participated in the study, 33 doctors were aware that the medical device could cause adverse events, however, 3 doctors were unaware of this. Out of 57 dentists who participated in the study 56 dentists had awareness about medical device adverse events. Of 75 pharmacists who participated in the study only 70 pharmacists were aware that medical devices could cause adverse events. However, all 42 nurses who participated in the study were aware that medical devices might cause adverse events. Below **Table 3** presents the data. It was observed that the few doctors, dentists and pharmacists who were not aware of medical device adverse events had work experience of 0 -5 years only.

Category of healthcare professionals	Aware (Number of participants)	Not aware (Number of participants)	Aware (Percentage of participants)
Registered Doctor	33	3	91.6%
Registered Dentist	56	1	98.2%
Registered Nurse	42	0	100%
Registered Pharmacist	70	5	93.33%

Table 3: Distribution of healthcare professionals based on awareness of medical devices adverse events.

4.1.2.2. Awareness of the Materiovigilance Programme of India (MvPI):

Out of 209 participants who responded to this question, only 37.8% of participants were aware of MvPI. However, 62.2% of participants were not aware of the MvPI. This data shows that overall awareness about MvPI was low among healthcare professionals in South India. Below **Figure 10** represents the data.

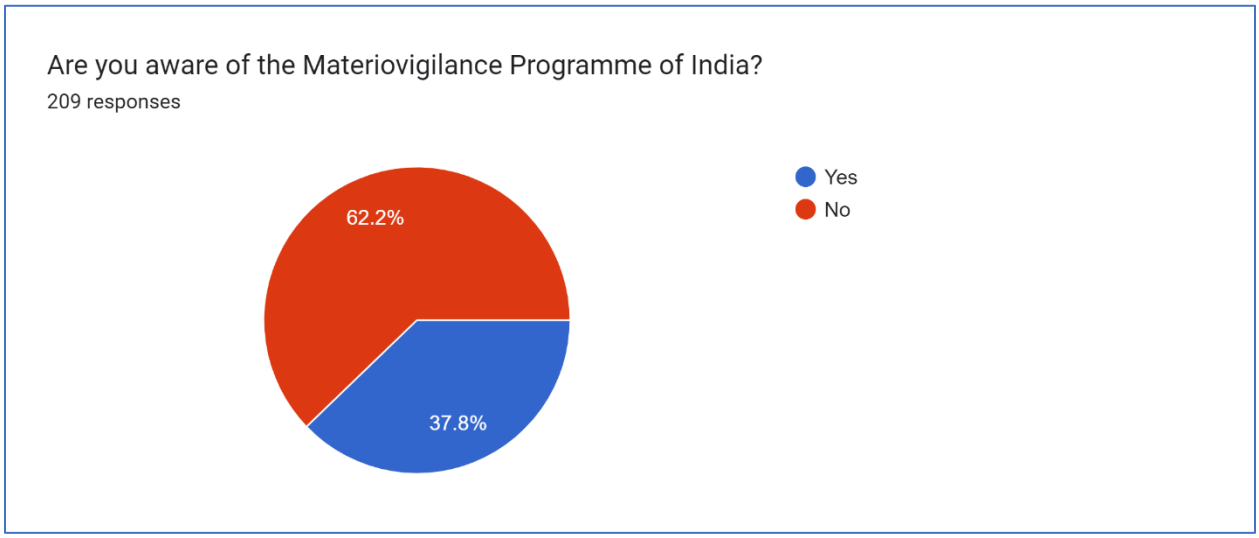

Figure 10: Pie-chart showing awareness of MvPI among study participants.

Out of 35 doctors who responded to this question, only nine doctors were aware of MvPI. The majority of doctors who participated in this study were not aware of MvPI. Out of 57 dentists who participated in the study only 16 dentists were aware of MvPI. Nearly half of the nurses who participated in the study were aware of MvPI. Out of 75 pharmacists who participated in the study 45.33% of pharmacists were aware of MvPI. The data is presented in below **Table 4**. The data

shows that the nurses who participated in the study had a higher percentage of awareness about MvPI compared to pharmacists and the doctors had the least percentage of awareness.

Category of healthcare professionals	Aware (Number of participants)	Not Aware (Number of participants)	Aware (Percentage of participants)
Registered Doctor	9	26	25.7%
Registered Dentist	16	41	28.07%
Registered Nurse	20	22	47.61%
Registered Pharmacist	34	41	45.33%

Table 4: Distribution of healthcare professionals based on categories on awareness of MvPI.

4.1.2.3 Awareness of medical device adverse event reporting form:

210 participants responded to this question. Nearly half of the participants were aware of the medical device adverse event (MDAE) reporting form. However, 51.9% of participants were not aware of the MDAE reporting form. This data shows that the healthcare professionals in South India had average awareness about MDAE reporting forms. Below **Figure 11** represents the data.

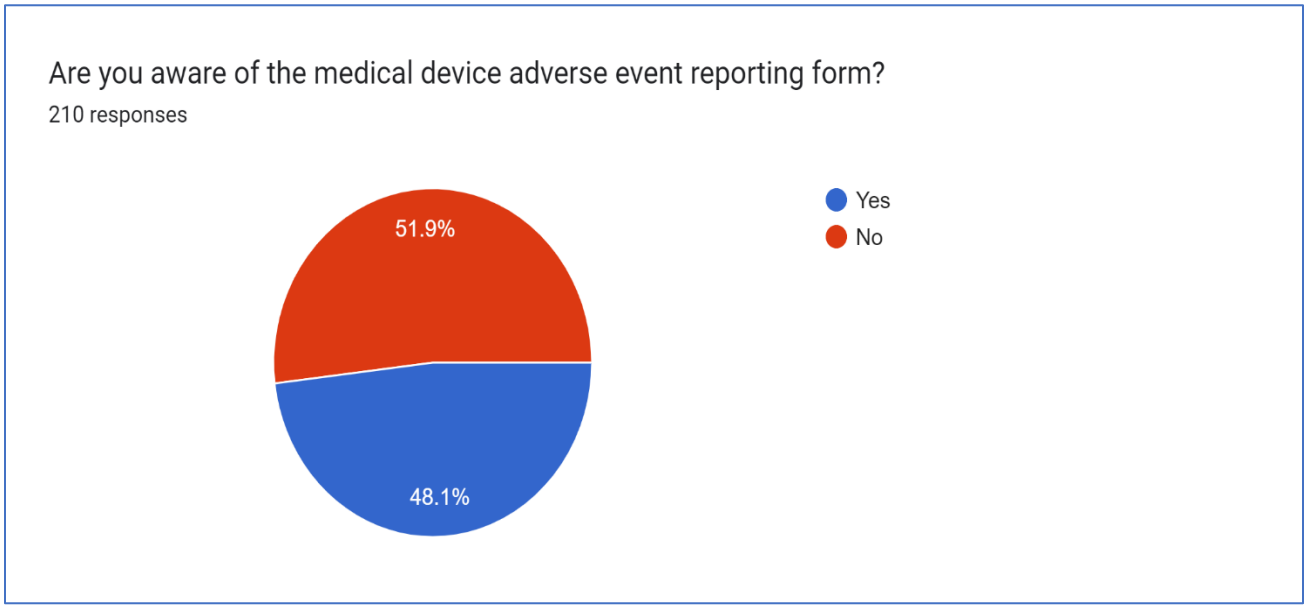

Figure 11: Pie-chart showing awareness of participants about medical device adverse event reporting form.

Out of 36 doctors who participated in the survey, 13 doctors were aware of the MDAE reporting form. However, out of 57 dentists who participated in the survey only 15 were aware of the MDAE reporting form. 29 nurses out of 42 who participated in the study were aware of the reporting form. 44 pharmacists out of 75 who participated in the study were also aware of the MDAE reporting form. The results showed that the nurses had more awareness about MDAE reporting form than doctors, pharmacists and dentists. The data is presented in **Table 5**.

Category of healthcare professionals	Aware (Number of participants)	Not Aware (Number of participants)	Aware (Percentage of participants)
Registered Doctor	13	23	36.11%
Registered Dentist	15	42	26.31%
Registered Nurse	29	13	69.04%
Registered Pharmacist	44	31	58.66%

Table 5: Distribution of healthcare professionals based on awareness of medical device adverse event reporting form.

4.1.2.4 Scenario based question 1 (Sterile device X with a caution label):

In the scenario-based question, a sterile device 'X' with a caution label of 'do not use if the package is opened or damaged' was discussed. The package of device 'X' was damaged prior to use and the device 'X' was not used. As per the majority of the survey participants, this event was reportable. However, as per the MvPI guidance document this event was not reportable (Indian Pharmacopoeia Commission, 2017a). Only 26.2% of participants suggested not to report this as an event. **Figure 12** represents the data. This data suggested that there was a lack of awareness about materiovigilance regulations and MvPI among healthcare professionals in South India.

In this survey question, 41.66% of doctors opted for the correct answer. Out of 57 dentists who participated in the study, only 16 dentists selected the right answer. However, out of 42 nurses who participated in the study only one nurse opted for the right answer. 30.66% of pharmacists selected the right answer. The data is listed in **Table 6**. The data indicated that the doctors had better awareness about scenarios discussed in the MvPI guidance document while nurses had the least awareness.

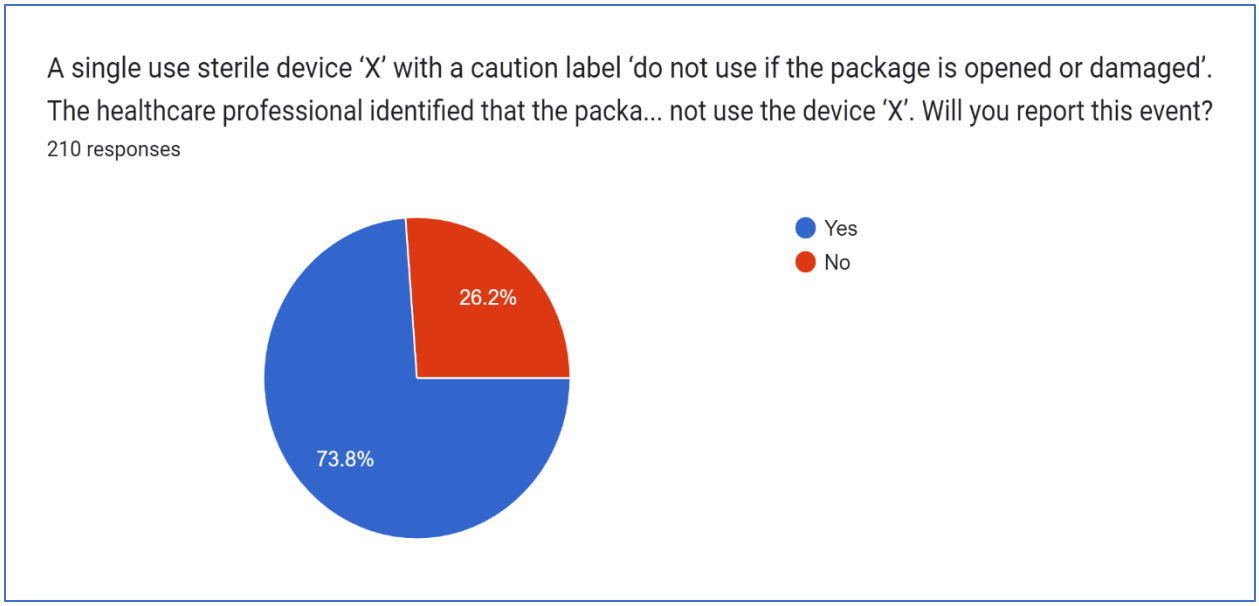

Figure 12: Image showing responses for scenario-based question of sterile device X.

Category of healthcare professionals	Right answer (Number of participants)	Wrong answer (Number of participants)	Right answer (Percentage of participants)
Registered Doctor	15	21	41.66%
Registered Dentist	16	41	28.07%
Registered Nurse	1	41	2.3%
Registered Pharmacist	23	52	30.66%

Table 6: Distribution of responses to scenario:1 by the healthcare professionals.

4.1.2.5 Scenario based question 2 (Patient with implant 'Z' had tissue reaction):

In scenario-based question 2, a patient implanted with an implant 'Z' experienced a tissue reaction (metal allergy) was discussed. 210 responses were obtained and 94.8% of the participants agreed to report this event. Only 11 participants out of 210 participants suggested not to report the event. This data suggests that the majority of the healthcare professionals who participated in the study were able to identify the adverse reaction and thus suggested reporting it. Below **Figure 13** represents the responses.

In this question, most of the healthcare professionals who participated in the study selected the correct answer. 32 doctors out of 36 who participated in the study agreed to report the event. 55

dentists, 40 nurses and 72 pharmacists agreed to report the adverse event indicating good knowledge on identifying adverse events. **Table 7** represents the data.

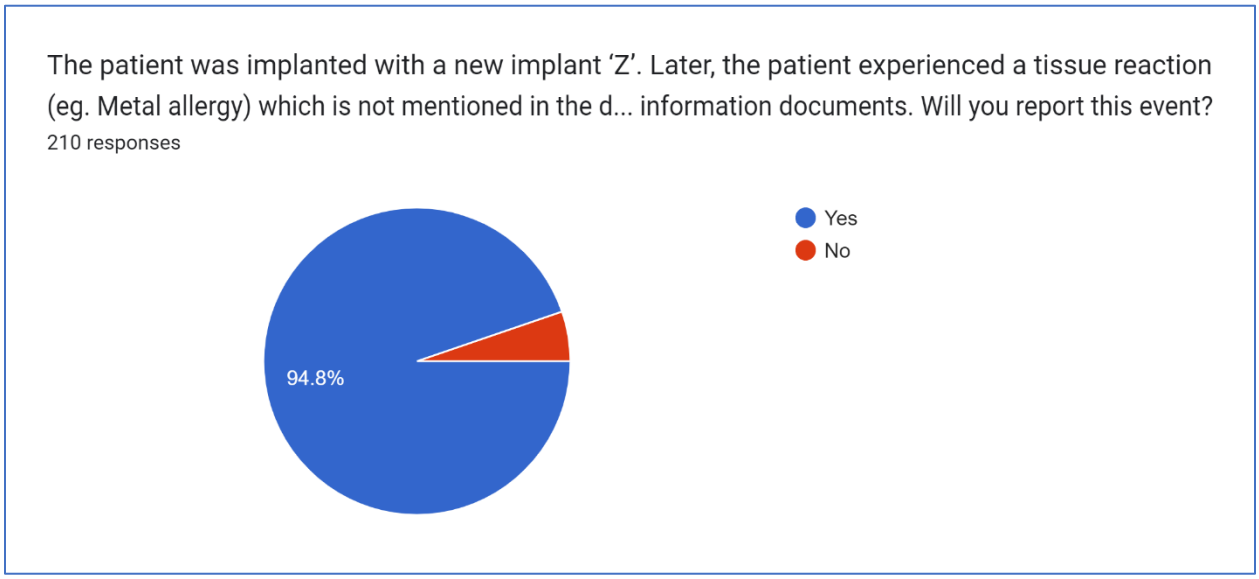

Figure 13: Image showing responses for scenario-based question of implant Z.

Category of healthcare professionals	Right answer (Number of participants)	Wrong answer (Number of participants)	Right answer (Percentage of participants)
Registered Doctor	32	4	88.88%
Registered Dentist	55	2	96.49%
Registered Nurse	40	2	95.23%
Registered Pharmacist	72	3	96.0%

Table 7: Distribution of responses to scenario:2 by healthcare professionals.

4.1.2.6 Reporting of medical device adverse events:

Out of 210 who agreed to participate in the survey, only 202 responded to this question. The response rate for this question was 96.19%. 78 participants were aware of all the methods of reporting like reporting to the medical device adverse event monitoring center (MDMC), adverse event monitoring center (AMC) and direct reporting to Indian Pharmacopoeia Commission (IPC). The remaining 124 participants selected either monitoring centers or IPC. This data suggests that only 38.6% of participants were aware of places to report medical device adverse events (MDAE). Thus, the knowledge about where to report MDAE was low. Below bar chart(**Figure 14**) represents

the data distribution. Of the 78 healthcare professionals who selected the right answer 27 were dentists however, 7 dentists who participated in this survey did not answer the question. Thus, it cannot be concluded that dentists had more awareness than other health professionals about reporting of MDAE. The number of participants who responded correctly in each category of healthcare professional is represented in **Figure 15**.

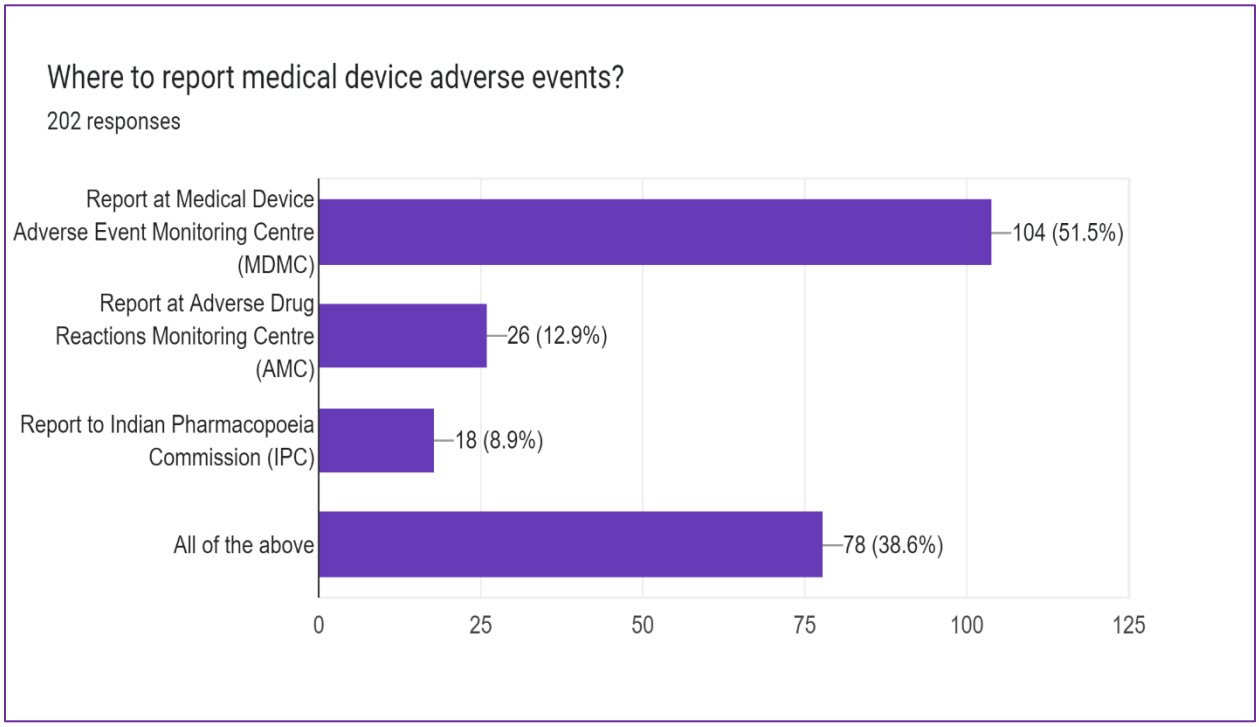

Figure 14: Bar chart representing knowledge about where to report medical device adverse events.

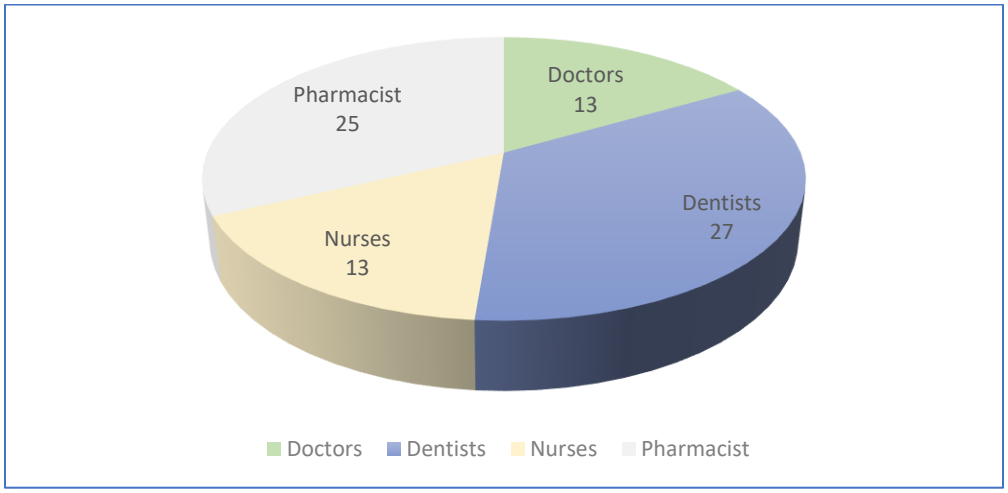

Figure 15: Pie-chart representing number of healthcare professional with knowledge regarding medical device adverse event reporting.

4.1.2.7 Medical device adverse event reporting tools:

In this question, the methods or tools to report a medical device adverse event was asked. The different methods included direct reporting, telephone, email and a mobile application. Only 200 participants responded to this question. The majority of participants opted for direct reporting by filling out medical device adverse event forms and submitting them to monitoring centers. 62 participants selected email as a method for reporting adverse events and 45 participants opted for direct telephone calls using the IPC helpline number. Only 21 participants selected the mobile application as a tool for reporting adverse events because of a lack of knowledge about the implementation of mobile app for adverse event reporting. However, all modes of reporting were selected by only 12 participants. The data is represented in **Figure 16**. This data suggests that the professionals had least knowledge about the medical device adverse event reporting process in India.

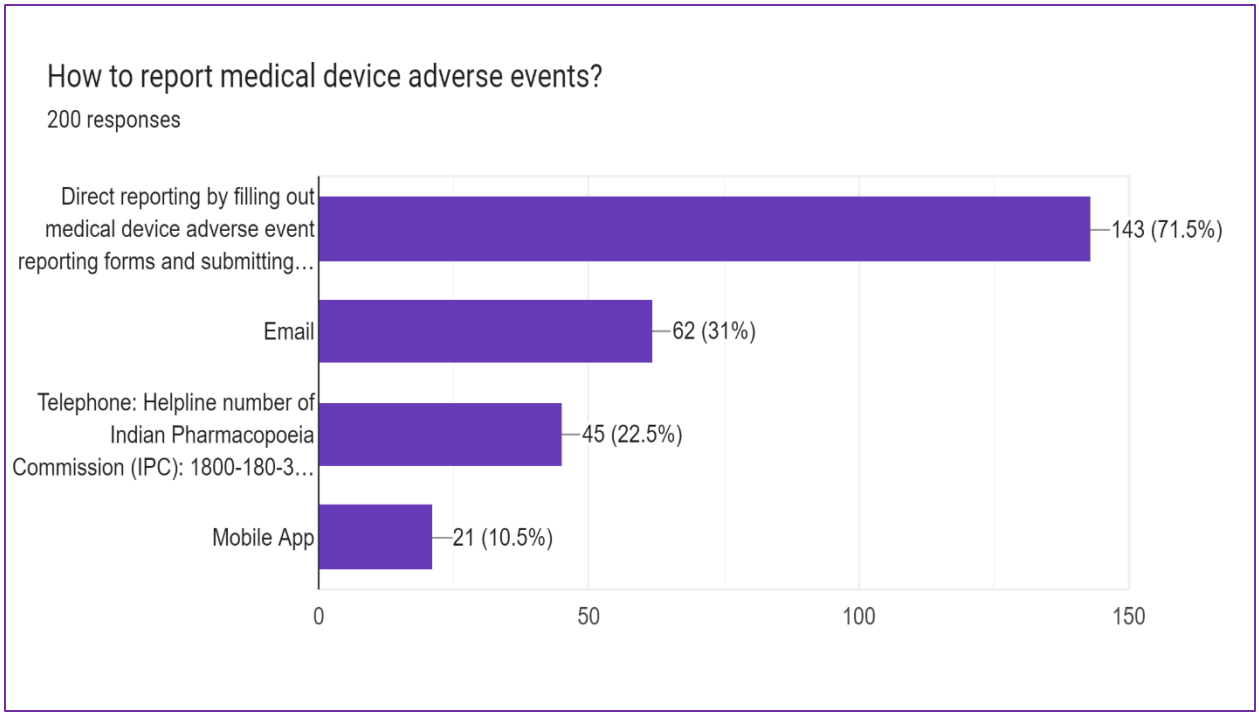

Figure 16: Bar chart representing knowledge about methods of reporting of medical device adverse events.

Only 12 participants were aware of all methods of reporting MDAE including 3 doctors, 2 dentists and 7 pharmacists. This clearly indicates the low knowledge of healthcare professionals about Materiovigilance in India.

4.1.2.8 Timeline for reporting serious medical device adverse events:

This question was answered by 200 participants and the majority of healthcare professionals selected the wrong answers. Only 4% of participants selected the 15 calendar days timeline of Indian regulations for reporting serious MDAE to national regulatory authorities. This indicates the lack of knowledge about medical device regulations among healthcare professionals. The data is represented in **Figure 17**.

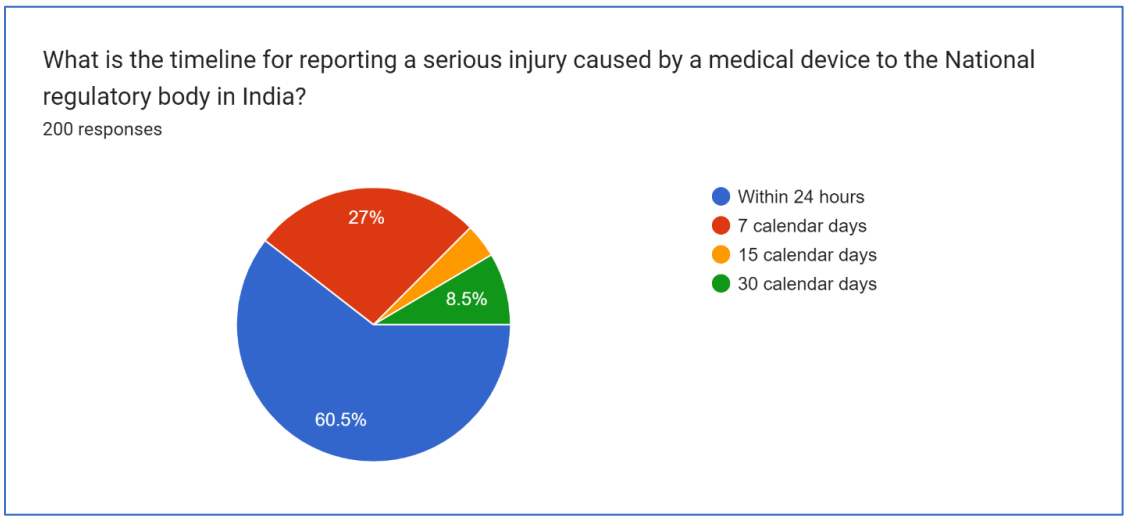

Figure 17: Pie-chart representing knowledge about timeline for reporting serious medical device adverse events.

4.1.2.9 Seriousness criteria for medical device adverse events:

A medical device adverse event becomes serious, if the event is fatal, life threatening or requires/prolongs hospitalization or cause disability/permanent damage or cause congenital anomaly/ birth defects or requires intervention to prevent permanent damage. 88.7% of participants were aware of all the seriousness criteria applicable for serious MDAE. This might be due to similarity between serious criteria of drugs and medical devices. The data is represented in **Figure 18**.

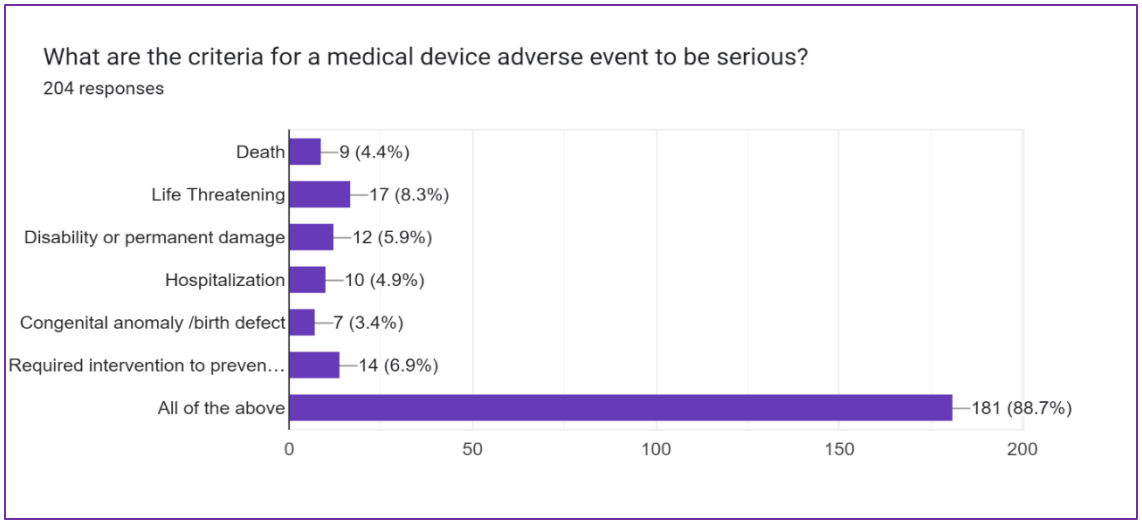

Figure 18: Bar chart representing knowledge about seriousness criteria for medical device adverse events.

91.66% of doctors responded correctly regarding assessing the seriousness criteria of adverse events. 96.1% of dentists had correct knowledge about the seriousness criteria of medical device adverse events however 5 dentists did not respond to this question. Out of 74 pharmacists who responded to this question, 67 pharmacists had good knowledge while only 31 nurses out of 42 nurses who participated in the study responded correctly. This indicates overall good knowledge among doctors, dentists and pharmacists. However, nurses had lesser knowledge about the seriousness criteria for medical device adverse events. The data is presented below in **Table 8**.

Category of healthcare professionals	Right answer (Number of participants)	Wrong answer (Number of participants)	Right answer (Percentage of participants)
Registered Doctor	33	3	91.66%
Registered Dentist	50	2	96.1%
Registered Nurse	31	11	73.80%
Registered Pharmacist	67	7	90.54%

Table 8: Distribution of healthcare professionals on knowledge about seriousness criteria.

4.1.2.10 Medical device alerts or recalls:

This question was answered by 205 participants. The question assessed the knowledge of healthcare professionals in South India about medical device alerts or recalls. Out of 205 participants only a small fraction of respondents was aware of medical device alerts or recalls. The

below pie-chart (**Figure 19**) presents the data. Out of 22 participants who were aware of medical device recalls or alerts, only a few participants mentioned a specific device. A nurse mentioned regarding alert or recall of syringes and cannula. An alert regarding an invitro diagnostic device 'combipack ABD' was mentioned by a pharmacist and a recall regarding covid test kit was mentioned by a dentist. The list of recalled or alerted devices are listed in below **Table 9**. The data showed that there was very poor knowledge among healthcare professionals regarding medical device recalls and alerts. The recalls or alerts are published on the official website of CDSCO however, there is a lack of awareness among doctors, dentists, nurses and pharmacists.

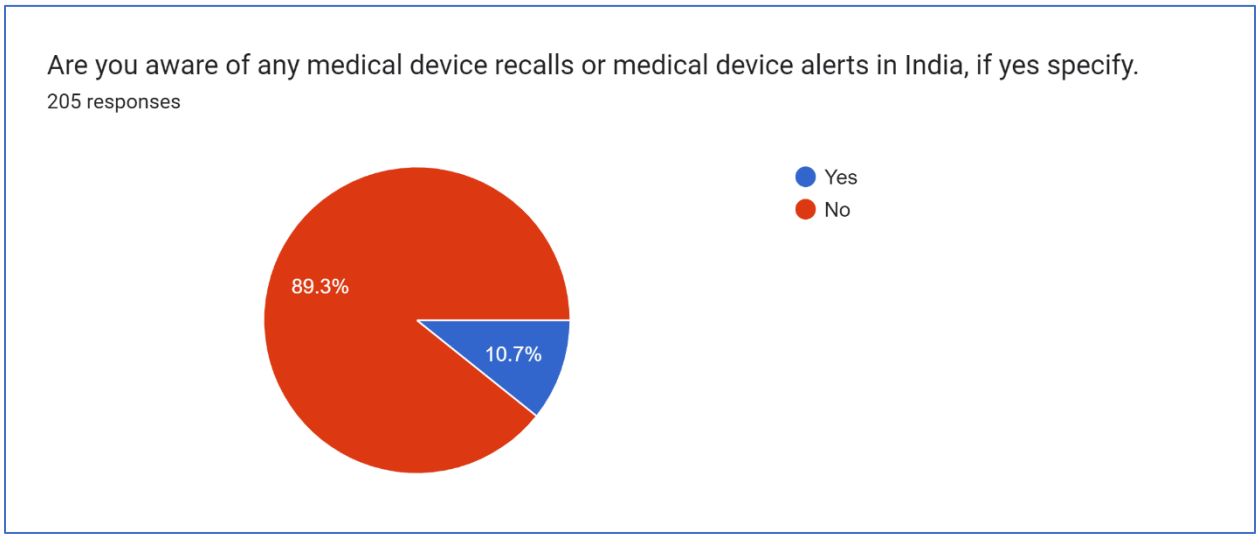

Figure 19: Awareness about medical devices recalls or alerts in India.

Medical devices list
Syringe
Cannula
Covid-19 test kit
Implant
Combipack ABD (IVD diagnostic kit)

Table 9: List of medical device alerts or recalls mentioned by respondents.

4.1.3. Assessment of Attitude:

4.1.3.1 Responsibility for reporting medical device adverse events:

30.2% of participants agreed with the statement that it was the responsibility of technicians and biomedical engineers to report MDAE and not of healthcare professionals. However, more than half of the participants disagreed with the statement while 16.1% of participants had a neutral opinion. The data is presented in **Figure 20**. The data suggested that more than half of the healthcare professionals who participated in the study showed a positive attitude towards the responsibility for reporting medical device adverse events.

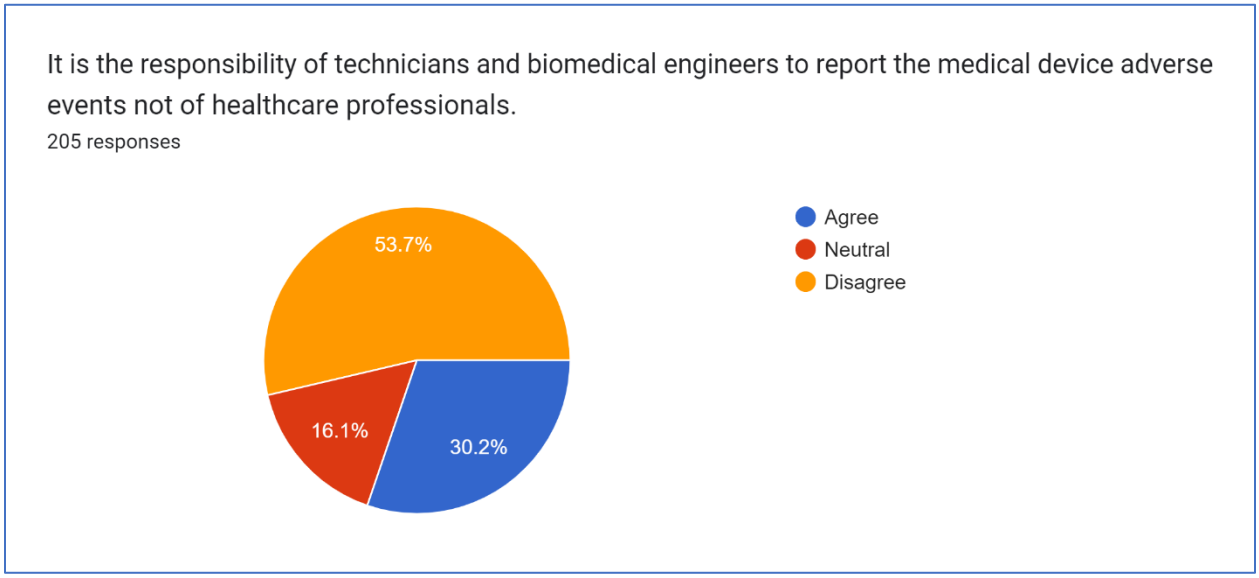

Figure 20: Pie-chart showing attitude towards responsibility to report medical device adverse events.

110 participants disagreed with the statement and had a positive attitude towards the responsibility of reporting MDAE. The number of doctors, dentists, nurses and pharmacists who responded positively is shown below in **Figure 21**.

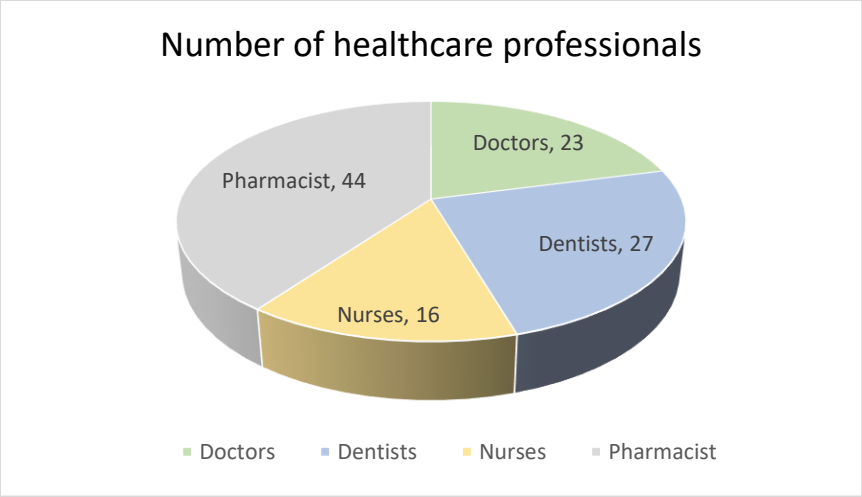

Figure 21: Number of healthcare professionals with positive attitude towards responsibility to report medical device adverse events.

4.1.3.2 Reporting of medical device adverse events and patient safety:

207 participants responded to this question. 96.6% of participants agreed with the statement that the reporting of MDAE enhances patient safety. However, 1.4% of participants disagreed with that statement and 1.9% of participants had a neutral opinion. This data showed that the majority of the healthcare professionals who participated in the study had a positive attitude towards reporting of MDAE and most of the participants believed that reporting of MDAE would improve patient safety. The data is shown in the below **Figure 22**.

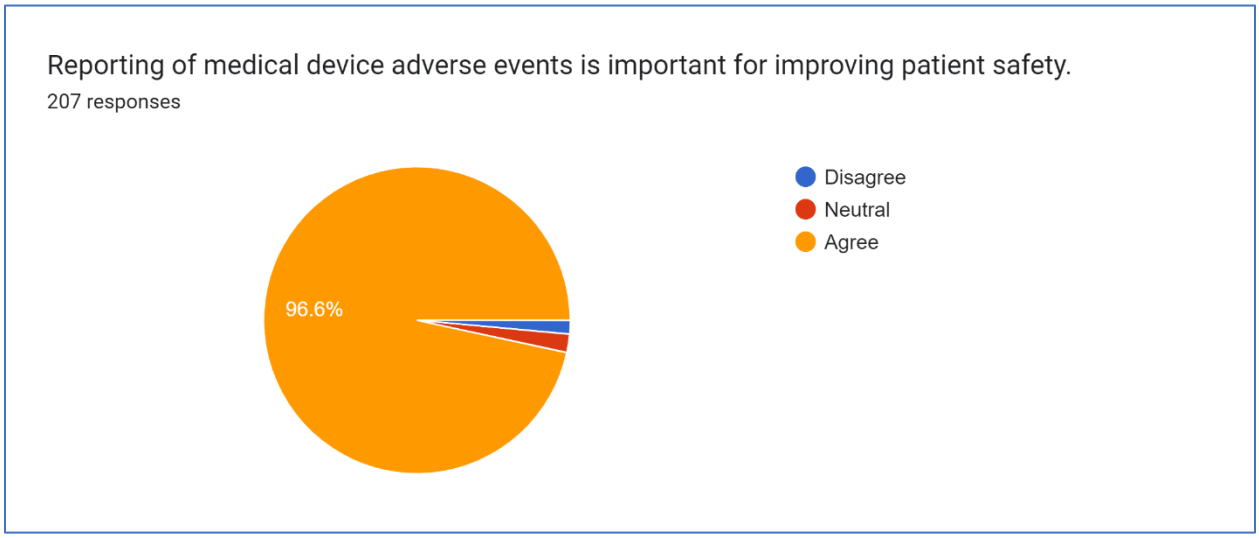

Figure 22: Pie-chart showing attitude towards reporting medical device adverse events to improve patient safety.

Out of 36 doctors who participated in the study 35 agreed that reporting of medical device adverse events improves patient safety. 52 dentists also had the same opinion. 41 nurses and 72 pharmacists also agreed that the reporting of medical device adverse events enhances patient safety. This data indicated a similar attitude among different categories of healthcare professionals towards reporting medical device adverse events to improve patient safety. The data is shown in **Table 10**.

Category of healthcare professionals	Total number of responses	Number of participants agreed	Percentage of participants who agreed
Registered Doctor	36	35	97.22%
Registered Dentist	56	52	92.85%
Registered Nurse	42	41	97.6%
Registered Pharmacist	73	72	98.63%

Table 10: Number and percentage of healthcare professionals with a positive attitude to reporting adverse events to improve patient safety.

4.1.3.3 Obligation to report medical device adverse events:

Out of 210 who participated in this study, only 205 responded to this question. 68.8% of participants agreed that the healthcare professionals had an obligation to report medical device adverse events (MDAE). According to 17.1% of participants, healthcare professionals did not have an obligation to report MDAE. However, 14.1% of participants were unsure about this. This data suggested that the majority of the healthcare professionals had a positive attitude towards reporting MDAE. The data is depicted in **Figure 23**.

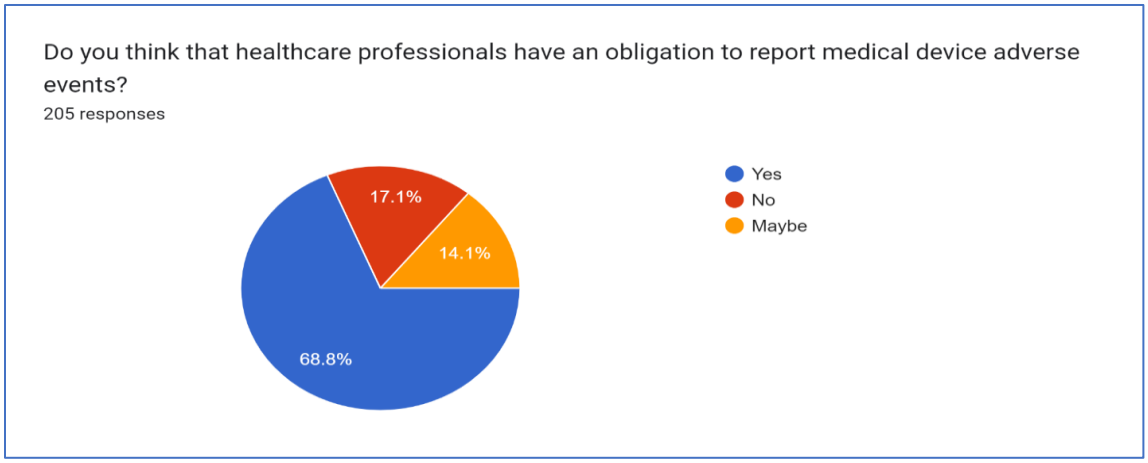

Figure 23: Pie-chart showing attitude of healthcare professionals towards obligation to report medical device adverse events.

In the group of participants who responded, 80.55% of doctors showed a positive attitude towards the obligation to report MDAE and 78.1% of dentists also had the same attitude. However, the percentage of participants with a positive attitude towards an obligation to report adverse events was slightly less among nurses and pharmacists. The overall data suggested a positive attitude among healthcare professionals. The data is shown in **Table 11**.

Category of healthcare professionals	Total number of responses	Number of participants agreed	Percentage of participants who agreed
Registered Doctor	36	29	80.55%
Registered Dentist	55	43	78.18%
Registered Nurse	42	24	57.14%
Registered Pharmacist	72	45	62.50%

Table 11: Number and percentage of healthcare professionals with a positive attitude towards the obligation to report adverse events.

4.1.4. Assessment of practice:

4.1.4.1 Medical device adverse event at work:

Out of 210 healthcare professionals who participated in the study only 207 participants responded to the question. 72% of healthcare professionals who responded to this question, did not observe

any medical device adverse event during their work. Only 58 participants had identified or observed a medical device adverse event. As per the data only a small number of participants identified and reported the adverse event. However, 5.8% of participants observed an adverse event but did not report it as the event was mild while 7.2% identified medical device adverse events but did not report it due to lack of knowledge of where to report it. The data suggested that the practice of materiovigilance was less among healthcare professionals in South India. The data is presented in **Figure 24**.

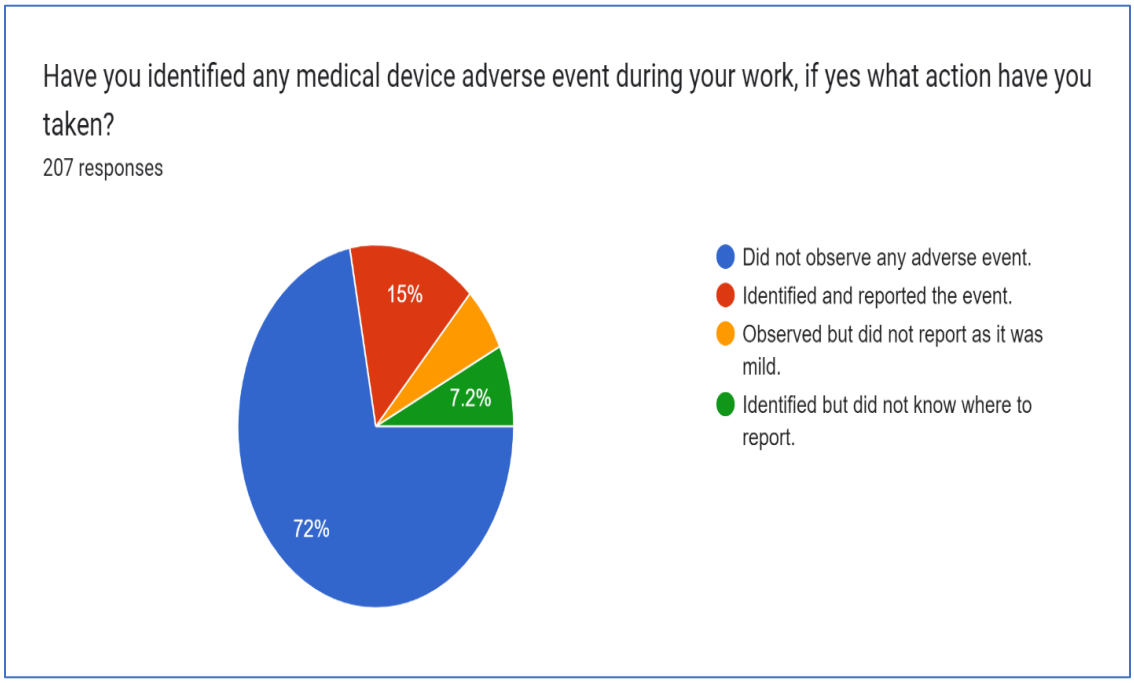

Figure 24: Pie-chart representing identification and action taken towards medical device adverse events by healthcare professionals.

Among different categories of healthcare professionals, nurses identified and reported more events compared to doctors, nurses and pharmacists. Even though dentists identified the adverse events, those were not reported as the events were mild and due to lack of knowledge of reporting. The data is represented in the below stacked bar graph (**Figure 25**).

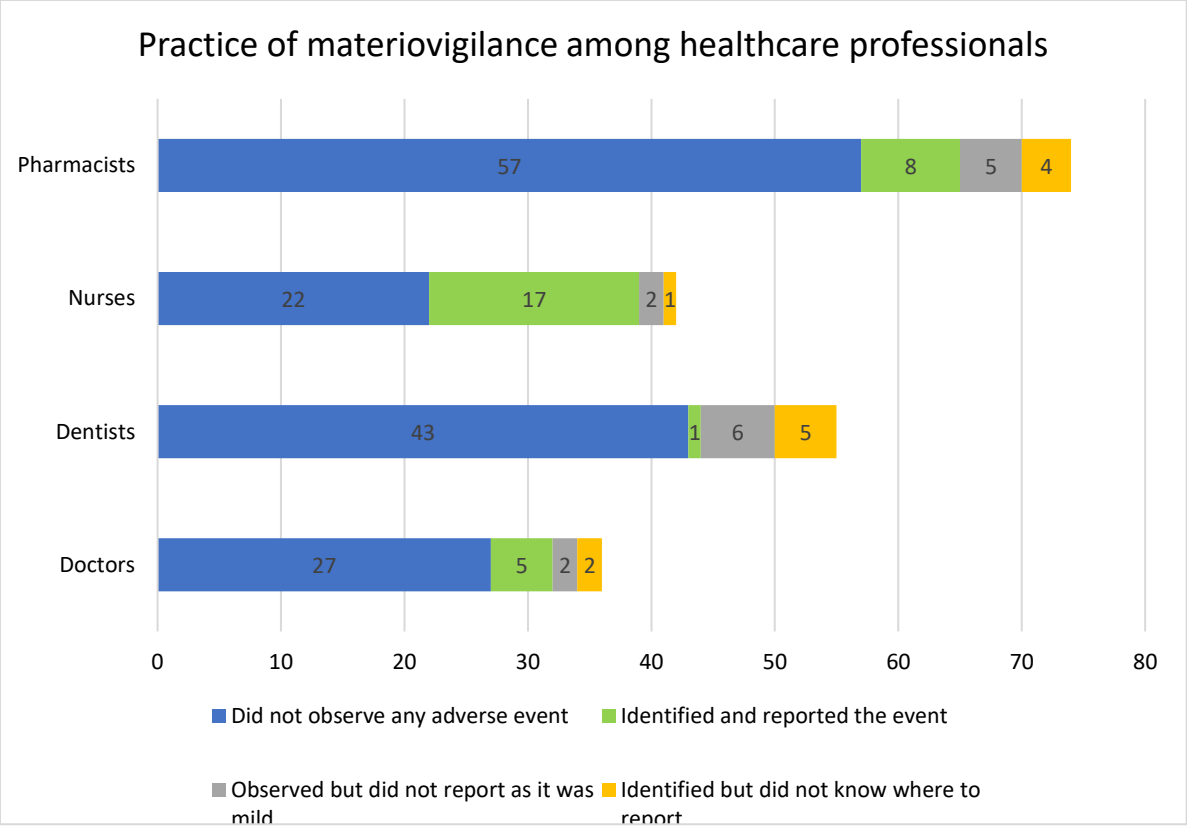

Figure 25: Stack-bar graph representing identification of adverse events and action taken by different categories of healthcare professionals.

4.1.4.2 Medical device adverse event form at workplace:

206 participants responded to this question. According to 44.7% of participants, the medical device adverse event (MDAE) reporting form was not available at their workplace. However, 27.2% of participants had the adverse event reporting forms at their workplace meanwhile 28.2% of participants were unsure about the same. The data is presented in **Figure 26**. The data suggests a lack of easy access to reporting forms among the healthcare professionals. As per the data, nurses had more access to medical device adverse event forms compared to pharmacists, doctors and dentists. The data is depicted in **Figure 27**.

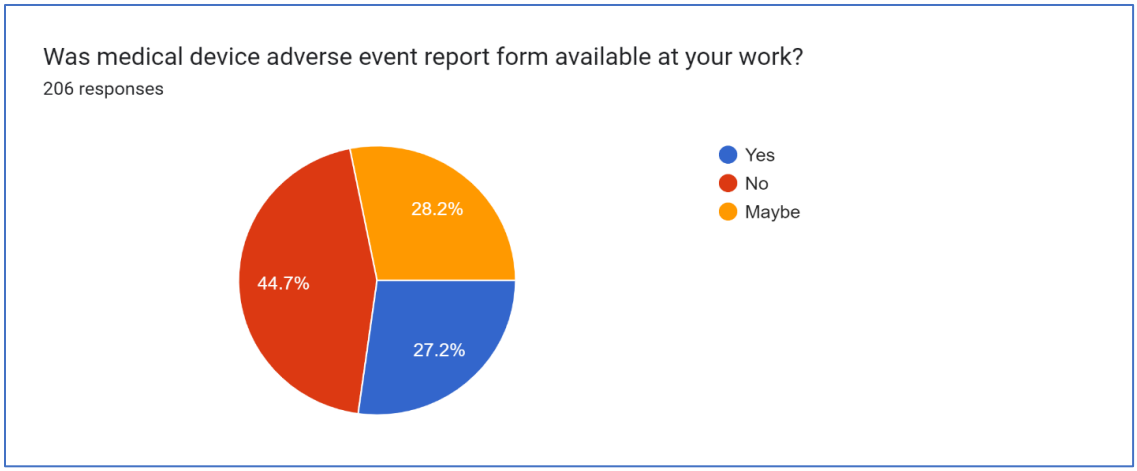

Figure 26: Pie-chart representing availability of medical device adverse event reporting form at workplace.

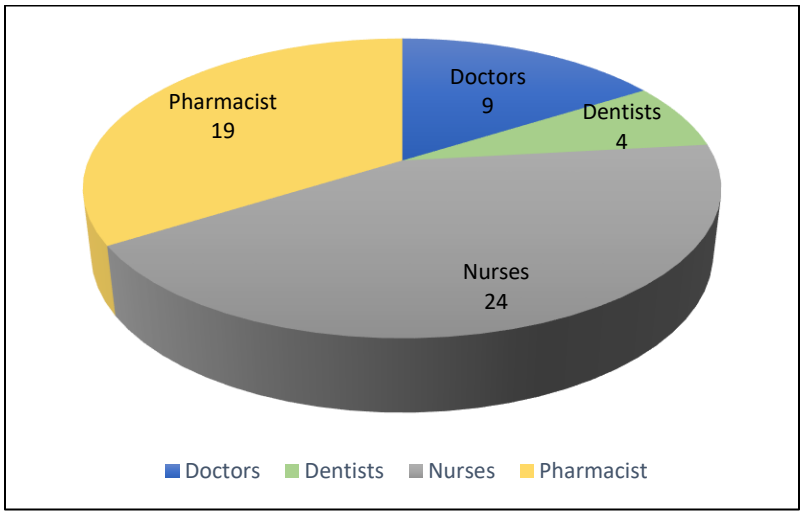

Figure 27: Number of healthcare professionals with medical device adverse event reporting form available at workplace.

4.1.4.3 Materiovigilance Programme newsletters:

The majority of participants (78.9%) had not read or seen Materiovigilance Programme newsletters published by IPC. Only 12.9% of participants had read or seen the newsletters while 8.1% were unsure about it. The data is presented in the pie chart (**Figure 28**). This data suggested that the awareness and practice of materiovigilance were low among healthcare professionals in South India. As per data, the awareness about newsletters was comparatively more among pharmacists.

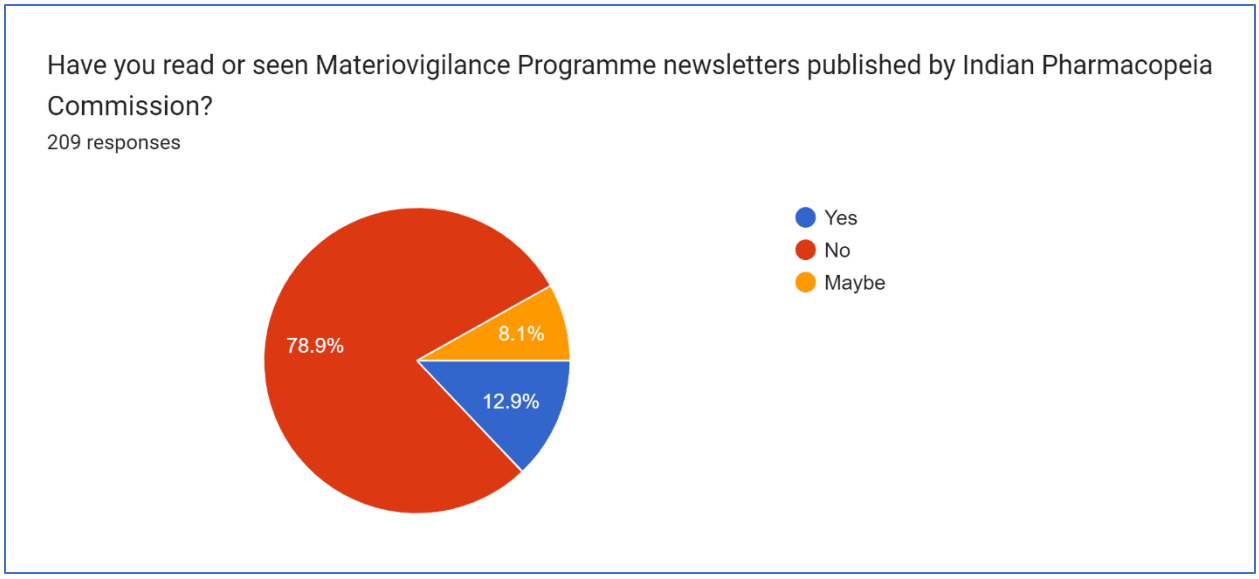

Figure 28: Awareness on Materiovigilance program newsletters.

4.1.4.4 Training and seminars on materiovigilance:

208 participants responded to this question. 92.8% of participants had not attended any seminars or training on materiovigilance. Only a very small proportion of participants attended seminars or training on materiovigilance. The data is represented in the below **Figure 29**. As per the responses, none of the dentists attended any training or seminars on materiovigilance. Only 1 doctor had attended training or seminar about materiovigilance. 7 pharmacists and 7 nurses who participated in the study were trained or had attended seminars. This data indicated that there was a lack of proper practice and education of materiovigilance among health professionals.

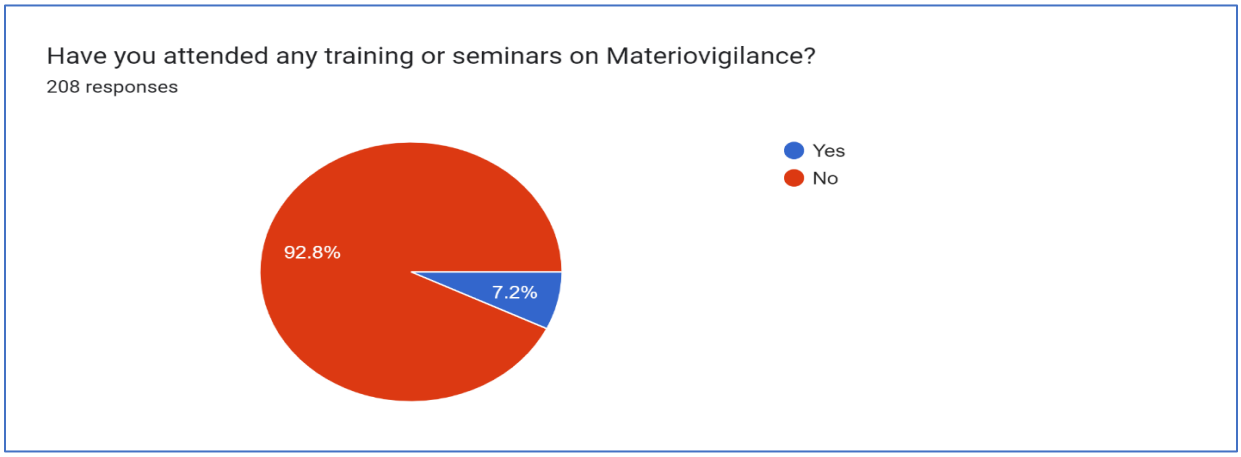

Figure 29: Pie-chart representing the participants based on training or seminar about materiovigilance.

4.1.5 Recommendations and opinions:

Out of 200 participants who rated the current medical device adverse event reporting system in India, 82 participants provided a rating of 3. Only 4 participants provided a maximum rating of 5 while 25% of the participants provided a minimum rating of 1. The data is represented in the below **Figure 30**. This data was in agreement with the assessment data as there were lacking in the practice and knowledge about materiovigilance in India.

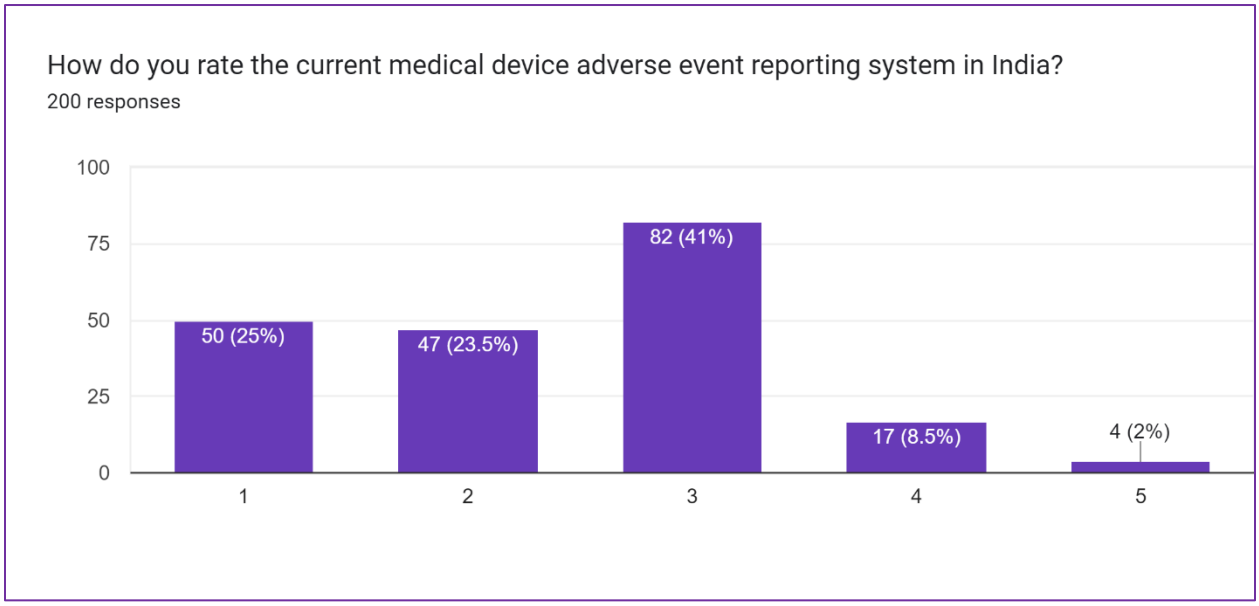

Figure 30: Ratings of current medical device adverse event reporting system in India.

As per the participants, the major gap in the current practice of Materiovigilance Programme of India (MvPI) was lack of proper training about materiovigilance which was also evident in the practice assessment section. Another reason that was pointed out by the majority of participants was lack of knowledge about the reporting process, which also agreed with the data obtained in the knowledge assessment section. 25.5% mentioned lack of easy access to AMC/MDMC for reporting. The participants also had concerns about legal issues. As per 13.2% of participants mentioned, lack of time was also a reason for underreporting. However, less than 10% of participants had an opinion that the professionals might not think that medical devices could cause adverse events. The data is presented in below **Figure 31**. This data suggested the need for more enhanced training, awareness and easy access to monitoring centers by increasing the number of reporting centers in each district.

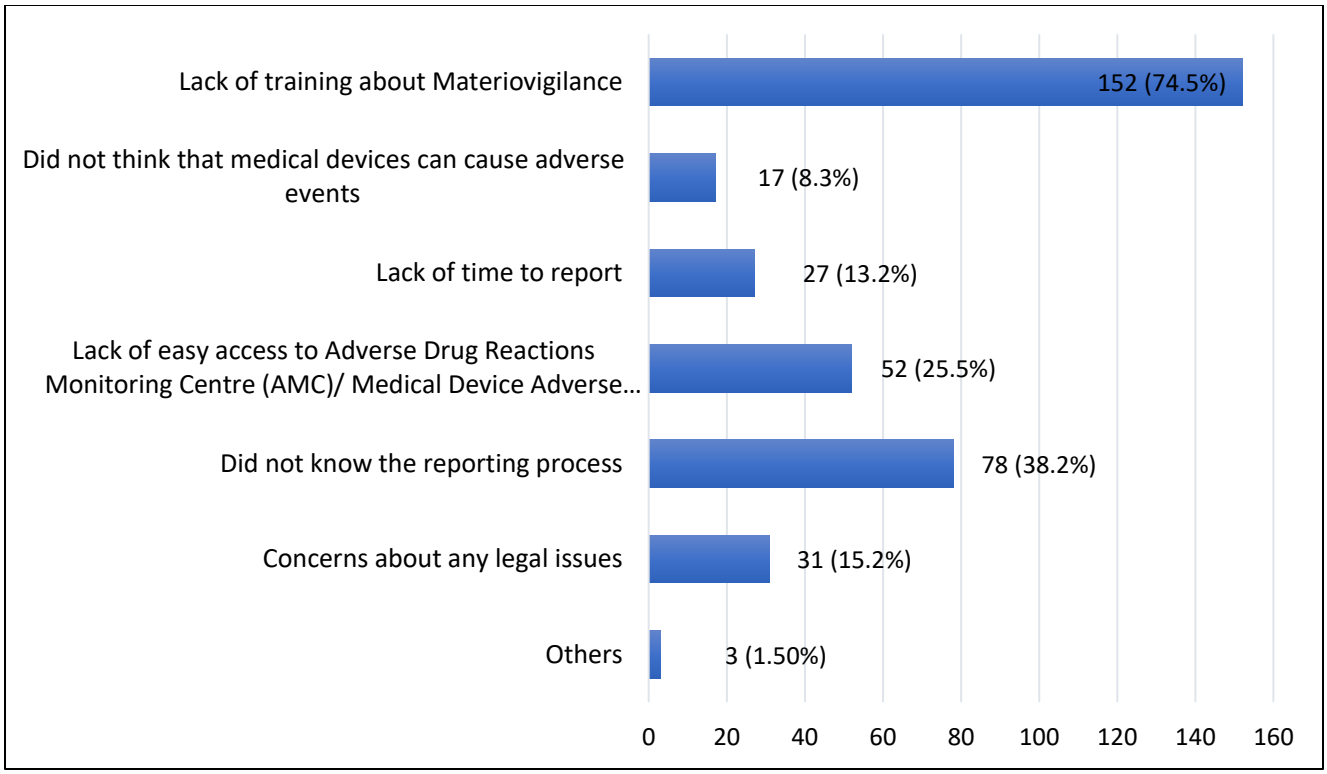

Figure 31: Gaps in current medical device adverse event reporting system in India.

Most of the participants recommended further training, seminars, workshops and awareness on the reporting process of materiovigilance among healthcare professionals. The suggestions also included the addition of materiovigilance in the education curriculum as well as to include in continuous education programs after graduation. Few changes were suggested in the materiovigilance process which included the need to make the reporting process easier, more access to monitoring centers, implementation of local helpline service working 24 x 7, integration of materiovigilance with pharmacovigilance and need for standard reporting procedure at workplaces. The respondents also highlighted the need for standard and qualified medical devices to enhance patient safety. There was a suggestion to implement a hospital-based system to monitor the reporting process. The healthcare professionals also suggested for encouraging reporting of adverse events and to promote medical device adverse event reporting process. The data is depicted in **Figure 32**.

Figure 32: Word cloud representing suggestions and opinions for further improvement of Materiovigilance in India.

4.1.6. Statistical analysis and hypothesis testing:

The data obtained in the survey was statistically analyzed and discussed in the below sections.

The relationship between level of knowledge and level of practice among healthcare professionals was tested using Pearson correlation.

Hypothesis: 1

Null hypothesis: There is no relationship between knowledge and practice of materiovigilance among healthcare professionals.

Alternate hypothesis: There is a relationship between knowledge and practice of materiovigilance among healthcare professionals.

Decision rule: Reject null hypothesis if P value (sig 2 tailed) is less than 0.05.

Correlations

		Knowledge	Practice
Knowledge	Pearson Correlation	1	.228**
	Sig. (2-tailed)		<.001
	N	210	210
Practice	Pearson Correlation	.228**	1
	Sig. (2-tailed)	<.001	
	N	210	210

**. Correlation is significant at the 0.01 level (2-tailed).

Figure 33: Correlation between Knowledge and Practice.

The correlation analysis is shown in **Figure 33**. The correlation analysis showed a positive correlation between knowledge and practice of materiovigilance. The Pearson correlation (r) is 0.288 and P value is <0.001 indicating statistically highly significant small correlation between knowledge and practice. Thus, the null hypothesis was rejected.

The below section analyzed the level of attitude about materiovigilance among healthcare professionals in South India.

Hypothesis: 2

Null hypothesis: The attitude towards materiovigilance will be negative.

Alternate hypothesis: The attitude towards materiovigilance will be positive.

Decision rule: The overall attitude score among healthcare professionals was between 0 to 9. If the mean attitude score is greater than 60% of total score (5.4) then the attitude is considered as positive, and the null hypothesis is rejected.

Category of healthcare professional	Mean attitude score (A)	Level of attitude
Registered doctors	7.944440	Positive
Registered dentist	7.649123	Positive
Registered nurse	7.071429	Positive
Registered pharmacist	7.546667	Positive

Table 12: Attitude score.

As summarized in **Table 12**, the average attitude score among all four categories of healthcare professionals were above 5.4 indicating a positive attitude. Hence, the null hypothesis was rejected.

The below section statistically compared the KAP score among different categories of healthcare professionals using Kruskal-Wallis test.

Hypothesis: 3

Null hypothesis: All categories of healthcare professionals have the same level of knowledge, attitude and practice of Materiovigilance.

Alternate hypothesis: Different categories of healthcare professionals have different levels of knowledge, attitude and practice of Materiovigilance.

Decision rule: If significance value (p value) is < 0.05 reject null hypothesis.

Category of healthcare professional	Mean knowledge score (K)	Mean attitude score (A)	Mean practice score (P)	Mean KAP score
Registered doctors	4.305555	7.944440	3.138889	5.129628
Registered dentist	4.245614	7.649123	2.578947	4.824561
Registered nurse	4.380952	7.071429	4.523810	5.325397
Registered pharmacist	4.733333	7.546667	3.360000	5.213333

Table 13: Table showing mean scores of knowledge, attitude and practice.

Category of healthcare professional.	Mean	Median	Kruskal-Wallis test (P-value)
KNOWLEDGE (K)			
Registered doctors	4.305555	4	**0.155**
Registered dentists	4.245614	4	
Registered nurses	4.380952	4	
Registered Pharmacist	4.733333	5	
ATTITUDE (A)			
Registered doctors	7.944440	9	**0.006**
Registered dentists	7.649123	8	
Registered nurses	7.071429	7	
Registered Pharmacist	7.546667	8	

PRACTICE (P)			
Registered doctors	3.138889	3	**<0.001**
Registered dentists	2.578947	2	
Registered nurses	4.523810	4	
Registered Pharmacist	3.360000	3	

Table 14: Comparison of KAP between different categories of healthcare professionals.

Level of Knowledge:

The mean knowledge score among 4 categories of healthcare professionals was almost similar. The median score is presented in the above **Table 14**. The P value calculated using the Kruskal-Wallis test was 0.155 thus the null hypothesis was retained. Thus, the level of knowledge among different categories of healthcare professionals was the same.

Level of Attitude:

The mean score of attitude and median scores were listed in the above **Table 14**. The mean attitude score was slightly higher among registered doctors compared to other categories. The group of doctors had the highest median score of 9 while the median score was 7 for nurses. As per Kruskal-Wallis test the P-value was 0.006 which was less than 0.05 thus null hypothesis was rejected. This indicated that there was a significant difference in the attitude scores among the four categories of healthcare professionals.

Level of Practice:

The mean practice scores and median practice scores were different among different categories of healthcare professionals. The group of nurses had higher mean practice scores of 4.523810 while dentists had the least mean practice score. The P-value was less than 0.001 indicating a significant difference in practice of Materiovigilance among healthcare professionals.

4.2. DISCUSSION:

Medical devices are widely used nowadays. Similar to drugs the safety of medical devices is essential to ensure patient safety. In India, a Materiovigilance Programme (MvPI) is in place to ensure safety of medical devices. However, materiovigilance and the concept of medical device

adverse events were not very popular among Indian population. In this present study, the extent of knowledge, attitude and practice about materiovigilance among 4 different categories of healthcare professionals were studied in South India.

In total 210 healthcare professionals including doctors, dentists, nurses and pharmacists from different parts of South India working in different sectors participated in this study. When compared to other studies which were conducted in a specific institution or a hospital among a group of nurses or doctors, this study included 4 categories of healthcare professionals from different hospitals, institutions and parts of South India (Manna *et al.*, 2023; T *et al.*, 2023; Tantia *et al.*, 2023.

4.2.1. Level of Knowledge, Attitude and Practice of Materiovigilance:

The study participants of this study had a below average knowledge about materiovigilance. The mean knowledge score of all 4 categories of healthcare professionals was less than 5 (out of 10). In this study 95.7 % of participants were aware that medical devices could cause adverse events. In a study conducted among nurses in Kolkata, 95% of nurses agreed that medical devices causes adverse events (Manna *et al.*, 2023), however in the present study 100% of nurses were aware of same. The awareness about MvPI was very low among the participants of this study which was in agreement with the data in studies conducted by Srinivas *et al.* and Meher *et al.* among doctors and nurses. In this study, only 48.1% of participants were aware of MDAE reporting form which is similar to the data obtained in a study conducted by T *et.al*. The percentage of participants responded correctly for scenario based questions for reporting adverse events were 26.2% (scenario 1) and 94.8% (scenario 2) respectively agrees with the study conducted in Asia pacific which showed that there is a perspective difference in identifying medical device adverse events among participants due to lack of knowledge (Yoon *et al.*, 2019). In the present study, the knowledge about where to report and how to report medical device adverse events were only 38.6% and 6% respectively which was very low which indicated the lack of knowledge on reporting process. The lack of knowledge of reporting process of medical devices was also highlighted in a study conducted among doctors in North India (Tantia *et al.*, 2023). Only 4% of participants in the present study had knowledge about the reporting timeline for serious medical device adverse events which was very low and was in agreement with the data obtained in a study conducted among doctors and nurses (Srinivas *et al.*, 2022). In the present study, 89.3% of

participants were not aware of any alerts or recalls of medical devices in India indicating lack of complete knowledge about the materiovigilance in India.

The healthcare professionals who participated in this study showed a very high positive attitude towards materiovigilance. The positive attitude towards reporting medical device adverse events were found in studies conducted by Manna *et al.,* T *et al.,* and Meher *et al.* However, there were also studies which showed very poor attitude towards materiovigilance among physicians in other parts of world (Gagliardi *et al.*, 2018). The majority of the participants of this study agreed that healthcare professionals had the responsibility and obligation to report medical device adverse events, thus increasing patient safety.

The data from this study indicated a poor practice of materiovigilance in South India among healthcare professionals. Only 15% of participants identified and reported medical device adverse events which was less compared to the reporting percentage of 27.14% among nurses in a study conducted by Manna *et al*. However, studies conducted among a group of nurses in South India in 2022 by Sivagourounadin showed a reporting percentage of only 4.5% and as per another study by Mehar *et al.* only 3.3% of doctors reported medical device adverse events. 78.9% of participants of this study had not seen or read newsletters published by IPC which has communications about medical device alerts, recalls and adverse events. 92.8% of participants of the present study had not attended training or seminars of materiovigilance. The lack of adequate trainings was identified among 89.7 % of participants in a study conducted among surgeons (Panchal *et al.*, 2022) and no training was reported by majority of participants in a study (Srinivas *et al.*, 2022). The level of practice of materiovigilance was very low. However, a positive relation was identified between knowledge and practice of materiovigilance.

Overall, the healthcare professionals had below average knowledge, high positive attitude and poor practice of materiovigilance in South India. The average KAP score of nurses is 5.325397 which was slightly high compared to other healthcare professionals while dentist had the lowest mean KAP score 4.824561.

4.2.2. Factors affecting Materiovigilance among healthcare professionals in South India:

41% of participants of this study provided a rating of 3 for the current materiovigilance process of India. The majority of the participants provided a rating equal to or less than 3 indicating gaps in

the current process. In this study, lack of training about materiovigilance and lack of knowledge on reporting process were identified as the main gaps of current process which was also highlighted in research studies of Srinivas *et al.,* Panchal *et al.,* and in a review article by Polisena *et al.* The participants of this study also indicated the lack of easy access to adverse event reporting or monitoring centers. Another reason highlighted by the participants of this study about under-reporting of MDAE was concerns of legal issues which was also mentioned by nurses working in Saudi Arabia in a study (Alsohime *et al.*, 2019).

4.2.3. Recommendations for improvement:

In this study few opinions and recommendations to improve the Materiovigilance process of India were obtained from the participants. The majority of healthcare professionals participated in the study recommended training by conducting training programs, workshops and seminars to increase awareness about materiovigilance. Moreover, the need for more trainings on materiovigilance was discussed in literatures (Sivagourounadin *et al.*, 2022); (Srinivas *et al.*, 2022). Another major recommendation was to educate the healthcare professionals by including the steps of reporting in the standard work procedures, by adding materiovigilance to the learning curriculum of undergraduate or post-graduate students and by adding this topic to continuing medical/dental education seminars. The addition of materiovigilance into curriculum was discussed in various studies (Manna *et al.*, 2023); (Tantia *et al.*, 2023). The participants also suggested to promote and encourage the reporting of MDAE. The study by Manna *et al.,* suggested promotion by using posters and newsletters. Another main practical suggestion obtained in the present study was to merge pharmacovigilance activities with materiovigilance activities in India. The participants also suggested the implementation of monitoring facility in each hospital. There were suggestions to simplify the reporting process to improve the Materiovigilance Programme in India. After 8 years of implementation of Materiovigilance Programme in India, the gaps in the process were evident which need to be eradicated.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

This study evaluated the knowledge, attitude and practice of materiovigilance in South India. The study also identified the major factors affecting medical device adverse event reporting and the study also included opinions from the study participants for further improvement of Materiovigilance Programme of India. This section includes a brief summary about the study and its findings followed by the significance of this study compared to already available data. This section also includes discussion of limitations of this study and recommendations for future research or study about materiovigilance.

5.1. Summary:

This study evaluated the level of knowledge, attitude and practice among doctors, dentists, nurses and pharmacists about materiovigilance using a quantitative method. This study was carried out by distributing survey questionaries among the healthcare professionals in South India. 210 healthcare professionals participated in the study. The findings of this study showed that the overall knowledge was below average about materiovigilance among healthcare professionals. All 4 categories of healthcare professionals had almost the same level of knowledge about materiovigilance. As per the data obtained in this study, all categories of healthcare professionals had a high level of positive attitude towards materiovigilance. However, the practice of materiovigilance was very poor among the healthcare professionals. A positive correlation was identified between the level of knowledge and level of practice of materiovigilance among the participants. Among 4 categories of healthcare professionals participated in this study, the group of nurses had the highest average KAP score indicating a better level of knowledge, attitude and practice of materiovigilance compared to other groups of healthcare professionals. The group of dentists had the lowest average KAP score. It was concluded that the participants of this study had a below average level of knowledge and a poor level of practice of materiovigilance even after 8 years of implementation of Materiovigilance Programme in India. However, all the participants showed a high level of positive attitude towards materiovigilance.

In this study the gaps in the current process of medical device adverse event reporting and monitoring in India was also studied using the questionnaire. Majority of the participants of this study rated the current practice of materiovigilance of India in a range of 1 to 3 (highest score was 5). The major gaps for poor practice of materiovigilance in India were lack of proper training about

materiovigilance, lack of awareness on the reporting process of medical device adverse events and lack of easy access to monitoring centers in the country. Few healthcare professionals who participated in the study had concerns about time and legal issues.

The study also aimed to provide recommendations for further improvement of Materiovigilance Programme in India. Opinions and recommendations were obtained from the study participants using an open-ended question in the survey as well as from the secondary data. The awareness about the Materiovigilance Programme could be increased by using promotions like posters in institutions. The knowledge about materiovigilance could be improved by providing training, seminars, workshops and continuous education programs for healthcare professionals. The regulatory authorities in India could combine the pharmacovigilance and materiovigilance activities which might improve the awareness and practice of Materiovigilance. The fear of legal issues could be avoided by making the reporting anonymous. These recommendations might help the concerned authorities in improving the practice of Materiovigilance in India.

5.2. Relevance of the study:

Based on secondary research, most of the studies about materiovigilance were conducted among the healthcare employees of a single hospital. In most of the studies, the institution was either a teaching hospital or a tertiary care hospital. This was identified as the major limitation in studies conducted by Manna *et al.,* Aloshime *et al.* and Srinivas *et al.* However, the present study had overcome this limitation as this study was conducted among healthcare professionals from various parts of South India working in different settings. Thus, better clarity was obtained compared to other studies conducted in a single institution.

Most of the previous studies were conducted among only nurses or doctors or surgeons. These studies mentioned this as a limitation and recommended to conduct the study among various categories of healthcare professionals to obtain a more clear understanding (Panchal *et al.*, 2022; Sivagourounadin *et al.*, 2022). As per literature review, there were no studies evaluating knowledge, attitude and practice of materiovigilance among dentists and pharmacists in India. The present study was conducted among four different categories of healthcare professionals namely doctors, dentists, nurses and pharmacists. Thus, this was the first study evaluating knowledge, attitude and practice of materiovigilance among different categories of healthcare professionals including dentists and pharmacists in South India.

In addition to above mentioned advantages, the present study also obtained recommendations and opinions for further improvement from the healthcare professionals themselves. These opinions could be implemented practically.

5.3. Limitations:

There were few limitations for this study. This study was conducted only for a short span of time due to time constraints. Due to this time issues only 210 healthcare professionals participated in the study. The participants could have been more. In this study 4 categories of healthcare professionals namely doctors, nurses, dentists and pharmacists were involved. Due to the busy work schedule of healthcare professionals the responses were received slowly. The number of each group of healthcare professionals participated in the study was not equally distributed and the number of doctors participated in the study was less compared to other categories. This might be due to the busy work schedule of doctors. In this study, opinions and recommendations for further improvement were obtained using an open-ended question. A detailed opinion and recommendations could have been obtained using an interview method. However, due to difference in time zones between India and Ireland it was difficult to conduct the interview among healthcare professionals.

5.4 Recommendations for future study:

Based on the findings and limitations of this study certain recommendations for future research and studies are discussed. In order to get a better and clear understanding of materiovigilance the study must be carried out for a longer period of time and with more number of participants. So, in future studies the sample size and study duration might be increased. Another suggestion for future studies is to use a mixed method of survey and interviews to obtain detailed recommendations for further improvement. Future research might be focused on activities to improve the knowledge and practice of materiovigilance among healthcare professionals. The findings obtained in this study can be used by healthcare professionals and regulatory bodies to initiate necessary actions to enhance practice of materiovigilance in India and increase patient safety. Since there is a positive relation between knowledge and practice of materiovigilance, the practice of materiovigilance can be improved by enhancing knowledge about materiovigilance among healthcare professionals.

CHAPTER 6: REFERENCES

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APPENDIX:

APPENDIX A: SURVEY

STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICE OF MATERIOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN SOUTH INDIA

Dear Participant,

My name is Liz Paul. I am studying MSc Pharmaceutical Business and Technology at Griffith College, Dublin Ireland. This survey is a part of my dissertation to evaluate the Knowledge, Attitude and Practice of Materiovigilance among healthcare professionals in South India.

Materiovigilance means adverse event reporting and monitoring of medical devices. Currently, the use of medical devices has increased significantly. Thus, it is necessary to ensure the safety of medical devices. As a healthcare professional, you are invited to participate in this survey.

This survey has five parts. The first part is for participant demographics. Parts two to four evaluate the knowledge, attitude and practice of Materiovigilance. The final part is aimed to identify gaps and opinions to improve medical device adverse event reporting. The survey will take approximately 10 to 12 minutes to complete.

Please note: Participation in this survey is voluntary and you can withdraw at any time. All information and opinions provided will be treated confidentially and will be used only for research purposes.

Thanks in advance.

For more information, please contact: liz.paul@student.griffith.ie

I understand the purpose of this study. *

☐ Agree

I voluntarily agree to participate in this survey. *

- [ ] Agree

Part 1: General information/ Personal information

Description (optional)

What is your age group?

- ( ) 21-30 years
- ( ) 31-40 years
- ( ) 41-50 years
- ( ) Above 50 years

Which category of healthcare professional do you belong to? *

- ( ) Registered Doctor
- ( ) Registered Dentist
- ( ) Registered Nurse
- ( ) Registered Pharmacist

How many years of working experience do you have?

- 0 to 5 years
- 6 to 10 years
- 11 to 15 years
- Above 15 years

Part 2: Knowledge assessment

Description (optional)

Are you aware that medical devices can cause adverse reactions?

- Yes
- No

Are you aware of the Materiovigilance Programme of India?

- Yes
- No

Are you aware of the medical device adverse event reporting form?

- ○ Yes
- ○ No

A single use sterile device 'X' with a caution label 'do not use if the package is opened or damaged'. The healthcare professional identified that the package was damaged prior to use and did not use the device 'X'. Will you report this event?

- ○ Yes
- ○ No

The patient was implanted with a new implant 'Z'. Later, the patient experienced a tissue reaction (eg. Metal allergy) which is not mentioned in the device 'Z' information documents. Will you report this event?

- ○ Yes
- ○ No

Where to report medical device adverse events?

- ☐ Report at Medical Device Adverse Event Monitoring Centre (MDMC)
- ☐ Report at Adverse Drug Reactions Monitoring Centre (AMC)
- ☐ Report to Indian Pharmacopoeia Commission (IPC)
- ☐ All of the above

How to report medical device adverse events?

- [ ] Direct reporting by filling out medical device adverse event reporting forms and submitting them to monit...
- [ ] Email
- [ ] Telephone: Helpline number of Indian Pharmacopoeia Commission (IPC): 1800-180-3024
- [ ] Mobile App

What is the timeline for reporting a serious injury caused by a medical device to the National regulatory body in India?

- ( ) Within 24 hours
- ( ) 7 calendar days
- ( ) 15 calendar days
- ( ) 30 calendar days

What are the criteria for a medical device adverse event to be serious?

- [ ] Death
- [ ] Life Threatening
- [ ] Disability or permanent damage
- [ ] Hospitalization
- [ ] Congenital anomaly /birth defect
- [ ] Required intervention to prevent permanent Impairment/damage device
- [ ] All of the above

Are you aware of any medical device recalls or medical device alerts in India, if yes specify.

- ( ) Yes
- ( ) No

If Yes specify.

Short answer text

Part 3: Attitude assessment

Description (optional)

It is the responsibility of technicians and biomedical engineers to report the medical device adverse events not of healthcare professionals.

- ○ Agree
- ○ Neutral
- ○ Disagree

Reporting of medical device adverse events is important for improving patient safety.

- ○ Disagree
- ○ Neutral
- ○ Agree

Do you think that healthcare professionals have an obligation to report medical device adverse events?

- ○ Yes
- ○ No
- ○ Maybe

Part 4: Practice assessment

Description (optional)

Have you identified any medical device adverse event during your work, if yes what action have you taken?

- ◯ Did not observe any adverse event.
- ◯ Identified and reported the event.
- ◯ Observed but did not report as it was mild.
- ◯ Identified but did not know where to report.

Was medical device adverse event report form available at your work?

- ◯ Yes
- ◯ No
- ◯ Maybe

Have you read or seen Materiovigilance Programme newsletters published by Indian Pharmacopeia Commission?

- ◯ Yes
- ◯ No
- ◯ Maybe

Have you attended any training or seminars on Materiovigilance?

- ◯ Yes
- ◯ No

Part 5: Opinion/ Recommendations

Description (optional)

How do you rate the current medical device adverse event reporting system in India?

	1	2	3	4	5	
Minimum	◯	◯	◯	◯	◯	Maximum

What are the gaps in India's current medical device adverse event reporting system among healthcare professionals?

- [ ] Lack of training about Materiovigilance
- [ ] Did not think that medical devices can cause adverse events
- [ ] Lack of time to report
- [ ] Lack of easy access to Adverse Drug Reactions Monitoring Centre (AMC)/ Medical Device Adverse Event...
- [ ] Did not know the reporting process
- [ ] Concerns about any legal issues
- [ ] Other...

Do you have any suggestions or opinions to improve the medical device adverse event reporting system in India?

Long answer text

APPENDIX B: ETHICS FORM

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICE OF MATERIOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN SOUTH INDIA.

RESEARCHER'S NAME: Liz Paul

PROGRAMME OF STUDY: MSc In Pharmaceutical Business & Technology

SUPERVISOR'S NAME: Eucharia Esemuede

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:
STUDENT SIGNATURE:
DATE: 22-Jun-23

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes [ ] No [x]
SUPERVISOR SIGNATURE:
DATE: 28/06/2023

For Ethics Committee (if required):
Ethics Committee Approval Given: Yes [ ] No [ ]
ETHICS COMMITTEE MEMBER SIGNATURE:
DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and Objectives of Research.

Materiovigilance is the adverse event reporting of medical devices. In the current world, the use of medical devices is significantly increased. There were multiple incidences of adverse reactions and recalls of medical devices globally. In India, there were adverse reactions due to hip implants. In India, there were also reports of death and burn injuries of infants due to overheating of incubators. As there was a rise in adverse events due to medical devices, the Materiovigilance Programme of India (MvPI) was initiated in 2015. It is necessary that healthcare professionals are aware of Materiovigilance and its regulations. Multiple studies have already assessed the knowledge, attitude and practice of pharmacovigilance among healthcare professionals. However, very few published studies were available for Materiovigilance and with a limited number of participants. Thus, it is significant to carry out a knowledge, attitude and practice assessment about Materiovigilance among doctors, nurses, pharmacists and dentists in South India after 8 years of implementation of the Materiovigilance Programme in India. The key objectives of this study are as follows:

1. To carry out a literature review of articles discussing medical device adverse event (MDAE) reporting and regulations published from 2015.
2. To determine the extent of knowledge, attitude and practice of Materiovigilance among healthcare professionals in South India using a questionnaire.
3. To identify the gaps or factors that affect MDAE reporting by healthcare professionals in South India.
4. To analyze the data and provide recommendations for further actions if required.

1.2 Research methodology:

The primary research plan for this study is a quantitative method using a survey. The plan is to use a self-administered questionnaire prepared based on relevant sources of information such as literature articles and regulations. The proposed survey questionnaire will have 5 parts. In part 1, the personal information of the study participant will be collected which includes profession, years of experience and age group. Part 2 will assess the knowledge of participants using multiple-choice questions and scenario-based questions. Part 3 will have questions to assess the attitude of participants towards Materiovigilance by using closed-end "yes or no" questions. In part 4, questions to evaluate the practice of Materiovigilance among participants will be included. In part 5, an open-ended question will be asked to provide recommendations and opinions of healthcare professionals for further improvement in the practice of Materiovigilance. The questionnaire will be prepared in google forms and will be shared with a maximum number of healthcare professionals in South India using platforms like LinkedIn and WhatsApp. The plan is to compare the level of knowledge, attitude and practice among doctors, nurses, pharmacists and dentists. The data will be statistically analyzed.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18).

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

NA

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study.

The participants involved in this study are healthcare professionals namely doctors, nurses, pharmacists and dentists working in South India because the purpose of this study is to evaluate the knowledge, attitude and practice of Materiovigilance among healthcare professionals. Doctors, nurses, pharmacists and dentists deal with various medical devices in their daily work thus they must be aware of adverse events due to medical devices and its reporting.

4.2. How do you plan to gain access to/contact/approach your participant(s)?

The plan is to contact healthcare professionals using social media and networking platforms like LinkedIn and WhatsApp. Further, requesting the healthcare professionals who are in direct contact with me to share contacts of other healthcare professionals or to share survey links in their official groups.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2 **Informed Consent Form (ICF) for participants**

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

No: my research study involves an online survey only and/or does not require signed consent.

SECTION 6: STORAGE OF DATA

6.1. How will you store the research data and for how long? How will you manage data protection issues?

The collected data will be stored in a password-protected laptop. The raw data will be disclosed to the supervisor and will be submitted to the college in electronic format. The raw data will be archived for 2 years in secure folders and will be destroyed after 2 years.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST
NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	N/A
9.3 Questions/survey for interviewees/focus groups etc.	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

DATE: 22-Jun-23

SECTION 10: APPENDIX

APPENDIX: 1

TEMPLATE - Participant Information Letter or cover letter (Survey)

STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICE OF MATERIOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN SOUTH INDIA.

Dear Participant,

My name is Liz Paul. I am studying MSc Pharmaceutical Business and Technology at Griffith College, Dublin Ireland. This survey is a part of my dissertation to evaluate the Knowledge, Attitude and Practice of Materiovigilance among healthcare professionals in South India.

Materiovigilance means adverse event reporting and monitoring of medical devices. Currently, the use of medical devices has increased significantly. Thus, it is necessary to ensure the safety of medical devices. As a healthcare professional, you are invited to participate in this survey.

This survey has five parts. The first part is for participant demographics. Parts two to four evaluate the knowledge, attitude and practice of Materiovigilance. The final part is aimed to identify gaps and opinions to improve medical device adverse event reporting. The survey will take approximately 10 to 15 minutes to complete.

Please note: Participation in this survey is voluntary and you can withdraw at any time. All information and opinions provided will be treated confidentially and will be used only for research purposes.

Thanks in advance.

For more information, please contact: liz.paul@student.griffith.ie

I understand the purpose of this study.

I voluntarily agree to participate in this survey.