ANALYZING THE MEDICAL DEVICES-RELATED COUNSELLING PRACTICES AMONG INDIAN PHARMACISTS

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by

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Under the Supervision and Guidance of

Dr. Sudhinder Singh Chowhan

2023

DECLARATION BY STUDENT

I hereby declare that this dissertation titled '**ANALYZING THE MEDICAL DEVICES RELATED COUNSELLING PRACTICES AMONG INDIAN PHARMACISTS'** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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This is to certify that dissertation titled **'ANALYZING THE MEDICAL DEVICES RELATED COUNSELLING PRACTICES AMONG INDIAN PHARMACISTS'** is a record of the research work undertaken by Shivakshi Kiran Shah in partial fulfillment of the requirements for the award of the degree of MBA Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

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ABSTRACT

Medical devices refer to any device, apparatus, appliance, or object designed for use on individuals. Medical devices are a crucial component of Patient care and Healthcare systems. Medical technology is essential for the early detection, management, and therapy of diseases and ailments. Various regulatory frameworks are set up to regulate medical devices. Pharmacists are an important part of the Healthcare industry. They must counsel the patients and make them aware of the medical devices. The objective of this research is to examine how Pharmacists provide medical device advising. The research paper analyses the various studies conducted on home-use medical devices for a couple of months. A cross-functional study was conducted using a nationwide survey of community pharmacists working or owning a Local pharmacy, Franchise pharmacy, or Hospital pharmacy, and data were collected based on Random and Convenience sampling techniques. The findings suggest that pharmacists should prioritize education and training on the proper use of medicaldevices. Results show how devices are readily available on the market and how chemists respond to patients' requirements. Findings show chemists should keep up-to-date knowledge on how to utilize medical devices properly because patient inquiry is common. The current study found that self-reported counselling practices connected to medical devices were generally satisfactory to excellent. For a long-term objective, a more thorough future study is required to assess Pharmacist's real practice in this field. Government programs and various curriculums should focus on modernizing Pharmacist's knowledge and competencies and enhancing their impact on medical device assistance programs. The paper highlights the need for increased support for Pharmacists to provide counselling on prescription medicines, including training in communication skills and improved pharmacy design to provide more privacy.

Key words: Counselling, Customer, Medical Device, Pharmacists, Pharmacy

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ABBREVIATIONS

Abbreviation	Meaning
MRI	Magnetic Resonance and Imaging
USFDA	United States Food and Drug Administration
CDRH	Center for Devices and Radiological Health
EU	European Union
IMDRF	International Medical Device Regulators Forum
WHO	World Health Organization
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission
CDSCO	Central Drugs Standard Control Organization.
IVD	In Vitro Diagnostics
DCGI	Drug Controller General of India
DCA	Drug and Cosmetic Act
USD	United States Dollars
CAGR	Compound Annual Growth Rate
AI	Artificial Intelligence
R&D	Research and Development
OTC	Over the Counter
SD	Standard Deviation
MSME's	Micro, Small and Medium Enterprises

Chapter 1: Introduction

1.1 Overview of Medical Devices

1.1.1 Meaning of Medical Devices.

The rapid swift growth of Medical technology has impacted the Healthcare system in the present-day environment. Medical devices are regarded as a crucial component of Patient care and Healthcare systems. Medical technology is essential for Patient rehabilitation and the early detection, management, and therapy of diseases and ailments. (1)

Medical devices refer to any device, apparatus, appliance, matter, or object designed for use on individuals and incorporate the software essential for their accurate application, whether used alone or in combination for:

- illness detection, monitoring, treatment, or symptom relief,
- the identification, mitigation, supervision, and treatment of a medical condition or disability,
- research, evolving, or alteration of the physiology or anatomical structure,
- regulating the conception,

and, which helps in metabolic, immunological, and pharmacological activities but does not achieve fundamental intended action on individuals on its own. (2,3,4)

Therefore, there are many methods to employ medical devices. It could be used as an accessory for another medical device. Additionally, it may be customized as per individual needs and used as an active implanted device or for in vitro diagnostics.

Thus, Medical devices can be stated as small hypodermic needles, pacemakers, gloves, huge X-ray machines, MRI scans, etc. (5)

1.1.2 History of Medical Devices

The oldest instances of what we would consider medical equipment may be found in Baluchistan, where Neolithic humans practiced dentistry with flint-tipped drills and

bowstrings in 7000 BC. Additionally, it was discovered that Egyptians employed crutches, slings, splints, and other medical tools. Literature and archaeological discoveries also demonstrate that many medical devices were in use throughout the time of ancient Rome. (2)

A physician named Al-Zahrawia authored a book titled Kitab al-Tasrif in the 10th century in which he details several medical instruments used in his day to conduct operations. (6,7)

Figure 1.01 Medical devices mentioned in Kitab al- Tasrif.

The highly specialized medical device business today has roots in the early nineteenth century, while some of the medical gadgets from this era are still in use.

1.1.3 Regulatory Bodies for Medical Devices

Clinical investigation, production, and distribution of medical devices need to be governed every time for patient safety and care. Thus, new sets of guidelines are made to follow the processes of regulations. Various regulatory frameworks are set up across the world to check the reliability and effectiveness of claims of medical equipment.

In 1976, the Medical device act was amended to the USFDA. Today, the USFDA oversees the American medical device market.

The CDRH of the USFDA oversees businesses that produce, repackage, relabel, and/or import medical devices sold in the US. Additionally, the CDRH oversees managing the regulation of lasers, ultrasound equipment, and other medical and non-medical electronic devices that emit radiation. (8)

Other countries have distinct regulatory authorities, like EU members, Japan, and China. The

The Medical Device Directive was the first European device legislation, and it went into force in 1993. On May 26, 2017, the Medical Device legislation overtook the MDD as Medical Device Regulation (9)

The medical device industry has a wide range of participants, including producers, authorities, hospitals, doctors, and patients. To create standards that promote safety and lead to improved patient outcomes, it is crucial to include representatives from all stakeholder groups. The stakeholders can work together in a forum provided by ISO and IEC and other standards developers to create standards that facilitate compliance with the various regulatory frameworks in existence across the world while achieving these aims. (10)

To promote the global convergence of regulatory standards and practices, a network of national regulatory organizations called the International Medical Device Regulators Forum (IMDRF) was founded in 2011. The IMDRF aims to enhance standardized medical device quality, performance, and safety and serves as a forum for information exchange so that developing countries with medical device regulatory frameworks can pick up best practices from developed ones. Officials from the World Health Organization, as well as those in charge of Countries such as Australia, Japan, Brazil, China, Canada, the European Union, and the United States' medical device regulatory organizations, are among the IMDRF's members. (11)

Medical device regulation in India is handled by regulatory agencies. The foundation for medical device regulation is laid out in the Medical Device Rules, 2020. The DCGI-regulated medical devices and IVDs are under the Ministry of Health and Family Welfare.

The Indian Drugs and Cosmetics Act (DCA) of 1940, controls the efficacy and protection the Medical Devices. The DCA applies to medical devices that have been registered and that the government regularly classifies as pharmaceuticals. The DCA established MDR in 2017. The high standards of quality of this standard must be met by every manufacturer, supplier, and distributor of medical devices certified. Any medical equipment imported into India must comply with the CDSCO's Indian Medical Device Regulations. As of April 1, 2020, the updated MDR is applied to all Medical Devices As Newly Notified. There were only 37 distinct kinds of medical equipment that were regulated before the change. Registration certificates are required to guarantee the quality and claims of medical equipment.

As a result of Section 3(b)(iv) of the D&C Act, the Central Drugs Standard Control Organization (CDSCO) has been designated as India's primary regulatory authority for the import, sale, and production of medical devices. The CDSCO sets standards for medicines, cosmetics, diagnostics, and gadgets and grants licenses to producers and importers of pharmaceuticals. Additionally, it puts forth regulatory measures, amends Acts and Rules, and governs clinical research in India, requirements for imported medications, etc. in addition to market authorization for new drugs. To facilitate matters involving Notified Medical Devices, the CDSCO has established a distinct division named the Medical Device Division number. (12,13)

1.1.4 Medical device industry Market Overview

The medical device industry, which is one of the main sectors in the healthcare industry, is driven by innovation and modern technology. The expansion of new and improved technologies over the past few years has contributed to the creation of the latest medical technology as well as the growth and progress of the healthcare industry.

The global economy of today includes a significant portion of the medical device sector. The medical device business generated USD 550 billion in worldwide sales in 2022; according to projections in Figure 1.2, this market will increase at a CAGR of 5.5% in 2030 to reach USD 850 billion in sales. (14)

Figure 1.02 Medical Device Global Market Size (USD Billion).

The creation of new and proficient medical devices, together with simple regulatory clearance of such items, is probably to drive market growth for medical devices in the following years. Medical technology businesses are investing more money in R&D activities. Also, the growing global population aging, who will need extra care to maintain their health, the Increase in Global Incidence of some diseases such as Diabetes, Rise in the IVD market at the overall level. (15)

A rise in the need for devices with connectivity solutions, remote monitoring, and data management is observed. There is also a need for goods and services that boost the output of diagnostic laboratories. Adoption of innovative genomic technologies such as next-generation sequencing. Increase in investments in the IVD market due to government healthcare reform along with strong growth in Developing Nations like China and India. These are a few reasons for the growth of the Medical device industry. (16)

The increased need for innovative therapies and technical advancements in medical devices to fill unmet requirements in the healthcare sector is anticipated to be the main drivers of medical device growth over the next years.

Medical devices, on the other hand, are extremely costly due to their high purchase, maintenance, and ownership expenses. Additionally, some components of medical equipment require routine replacement, which raises the price. Since internet access is required to send patient data from remote devices to the doctor, security concerns related to data may hinder the growth of the medical device market. This has led to an increase in the threat to data security. The popularity of connected devices increases their needs, increasing the risk of hacking or data theft. (17)

A few trends that have been noticed include the rapid consumerization of diagnostics, the growth of telemedicine and digital health, the development of devices that enable personalized medicine, and the appearance of medical devices that are AI and robotics powered. Due to the increased emphasis on critical thinking by FDA, the computerized system validation process for medical device manufacturing will change.

The Medical Device market covers hospitals, ambulatory surgical centers, clinics, diagnostics centers, etc. based on end users. Hospitals and ambulatory surgery centers lead

the global market for medical equipment in 2021, according to the end user. In 2021, this category accounted for 88.5% of the overall revenue share. The significant expansion of the market is primarily driven by growing healthcare costs, expanding healthcare infrastructure, a strong focus on improving patient outcomes, and alluring reimbursement schemes.

Due to increased spending by both the government and the private sector on strengthening healthcare infrastructure in small and medium-sized health facilities and long-term care institutions around the world, the diagnostics centers market is rising at a CAGR of 10.3% from 2022 to 2030.

According to the regional distribution, in 2021, the North American market had a value of USD 188.14 billion. The existence of suitable and advantageous compensation practices, a strong medical care system, the quick uptake of innovative medical technology, and influential regional players are the main causes of its supremacy. This is strengthened much further by the rising incidence and prevalence of chronic illnesses in the area, as well as the rising number of people receiving diagnosis and treatment there. (18)

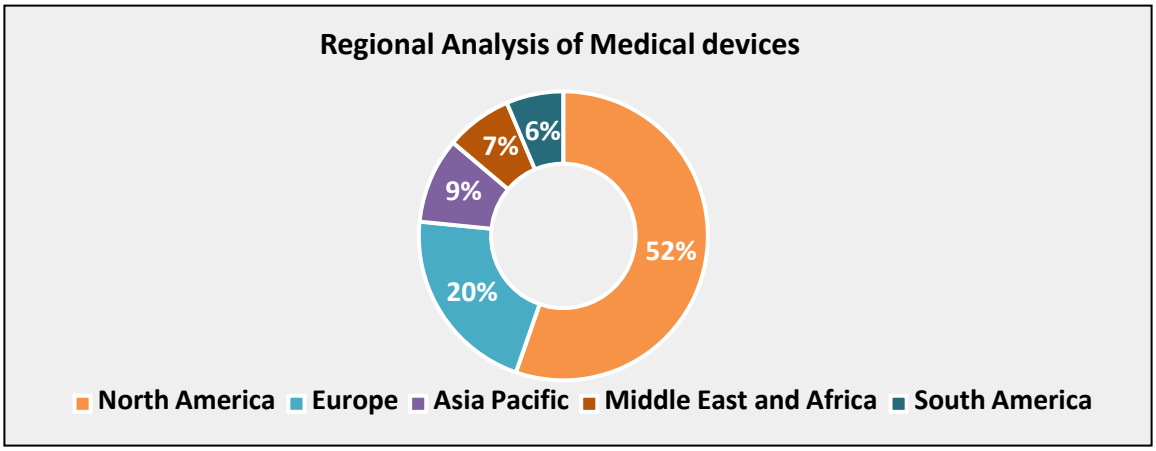

Figure 1.03 Doughnut graph depicting Regional usage analysis of medical devices

The United States is the most powerful and dominant nation in North America. The rapid adoption of new and innovative medical equipment for improving the detection and treatment of serious illnesses is what will drive market expansion in the area.

The European market is anticipated to see a high CAGR due to rising healthcare

expenditures, a reliable infrastructure, and the expanding use of advanced diagnostic and treatment equipment. Leading healthcare organizations have worked hard to make portable use of medical technology and move medical services to personal facilities.

Due to a significant emphasis on a change in medical services to personalized care settings and the introduction of portable medical equipment by leading regional and global firms in the surroundings, the market is anticipated to grow over the projected period.

Due to the rising incidence of conditions like heart disease, infectious diseases, orthodontic treatment disorders, and diabetic complications as well as the growing emphasis of market opponents on expanding their direct presence in developing nations like China and India and meeting the needs of patients in this region, Asia Pacific is projected to expand at a CAGR that is slightly higher than the average worldwide rate. (19)

When the market is divided based on the kind of medical equipment, the In-Vitro Diagnostics (IVD) sector is predicted to have a higher CAGR. This is due to an increase in the use of real-time diagnostic testing for the precise diagnosis of infectious and chronic diseases like cancer, diabetes, and other ailments. The other sector led the market in 2021 because of rising demand and usage for hospital supplies such as fetal monitors, surgical equipment, masks, gloves, and other medical equipment. The introduction of novel wound devices and bioactive treatments into the market is drawing increased investment from medical device companies, and this is expected to propel the growth of the wound treatment category at a significant CAGR. (20)

Technical advancements in the field of robotic surgeries and the increased use of these tools by medical experts are also projected to boost the expansion of the Minimally Invasive Surgery (MIS) industry. The growing patient population is ailing from various orthopedic and cardiac conditions worldwide, however, is expected to cause these above device markets to grow dramatically over the next years.

Additionally, it is anticipated that the increased incidence of diabetes and ophthalmic diseases in the general population would promote the use of ophthalmology and diabetic care equipment, eventually fueling the growth of the medical devices market throughout the course of the forecast period.

1.1.5 Indian Medical Device Market Overview

Small and medium-sized businesses (SMEs) and major international organizations are both represented in India's medical device industry, which is growing at a pace that is never seen. Currently, the country has 6000 different types of medical equipment and more than 250 MedTech startups.

India is among the emerging countries with the fastest-growing markets for medical devices because of rising medical technology demand, FDI influx, and export prospects.

According to estimates, India's medical device business is currently worth $12 billion and accounts for 1.5% of the worldwide medical device market. According to official statistics, the industry has had rapid growth in India, with a CAGR of 15% over the last ten years.

The Indian market for medical devices has the potential to expand by 28% annually to reach USD 50 billion by 2030, with an estimated $10 billion in medical device exports from India by 2025.

The Indian government has taken the following actions to promote the development of a thriving Indian medical device manufacturing ecosystem:

- The government has introduced production-linked incentive programs for medical equipment with cash incentives totaling $456 million to increase local manufacturing.
- New medical device parks are being built in Himachal Pradesh, Madhya Pradesh, Tamil Nadu, Telangana, and Uttar Pradesh to establish a strong manufacturing environment.
- Release of the National Medical Devices Policy and the National R&D Policy, which encourage multidisciplinary cooperation to enhance the development of translational capabilities and the start-up ecosystem, respectively, provide policy support.

For the analysis of Medical device segmentation based on its type, the highest revenue-generating medical device in India is Diagnostic Imaging with an amount of 30% followed by other Medical Devices, respectively. (21,22,23,24)

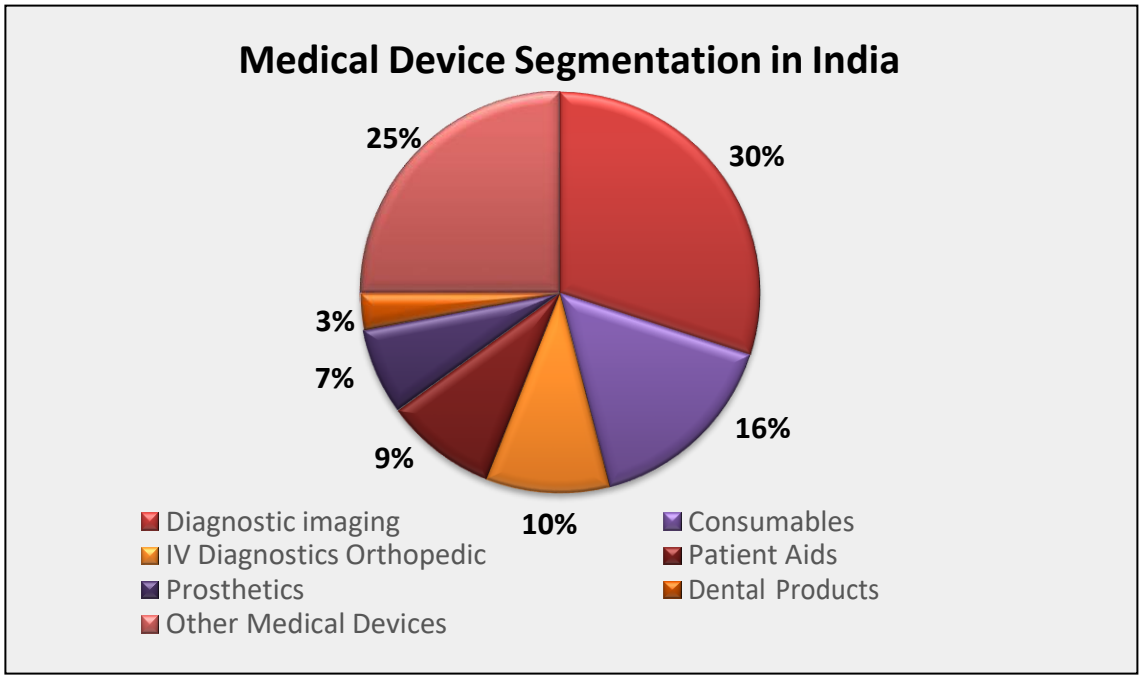

Figure 1.04 Pie chart showing Market Share of Medical Device Segmentation in India

1.1.6 Medical device classification globally

Classifying the medical device under the requirements of the relevant regulatory authority is a crucial step in receiving regulatory clearance. This categorization often denotes the designated degree of risk for the item. It also offers a plan for regulatory clearance, from design to development to market, whether that permission is required from the European Database on Medical Devices (EDMD) across the European Union or the US Food and Drug Administration (FDA).

Talking about USFDA, Three classifications were used to categorize medical devices. Devices like tongue depressors were included in class I of medical devices. These basic, non-life-sustaining devices fall under the category of general controls, which is the least restrictive kind of regulation. Class II medical equipment is those that need extra regulatory control, such as glucose meters, X-ray machines, and MRI scanners. These gadgets can harm people. The FDA has stricter requirements for approving certain medical devices. To be approved by FDA, these devices must adhere to both the General controls and Performance requirements. The last level, level III, contains items like pacemakers and artificial hearts. These are medical devices that are

essential to preserving life or avoiding human disability, making them the subject of the FDA's strictest regulation. (25)

Devices that meet the criteria for Class I and II may be exempt or not from the 501(k) premarket notification requirement. Premarket approval, a procedure used by the FDA to assess safety and efficacy, is normally required for Class III devices.

The European Commission Regulation, sometimes known as the Medical Device Regulation has four categories. Although there may be differences in the components of regulatory clearance, the classification tends to be more under global rules. Medical equipment that has been approved receives a CE mark, which is required to sell in Europe.

Non-invasive devices are classified as Class 1 (low to medium risk). Manufacturers are required to submit a Technical File as part of the approval procedure, although they often do not need certification from a Notified Body, an independent organization recognized by the EU to carry out regulatory audits and guarantee MDR standards are satisfied. These subcategories will require Notified Body assessment: Class 1s for sterile devices, Class 1m for low-risk measuring devices, and Class 1r for reused devices.

Devices having a Class IIa (medium risk) classification that is used inside the body for brief intervals (between 60 minutes and 30 days) must be examined by a Notified Body. (Medium to High Risk) Class IIb: Devices that pose a medium- or high risk and are placed into the body for at least 30 days must be reviewed by an authorized body.

Class III (high risk): The devices that will be continuously monitored by specialized institutions fall under this category. These devices will need to pass a thorough quality assurance system audit in addition to a Notified Body's inspection of the device and its design to be approved. (25,26)

In India, CDSCO governs the selling of Medical equipment and IVDs. The DCGI oversees CDSCO, while the State Licensing Jurisdiction and the Center Licensing Authority also have approval authority. The MDR 2017 Guidance serves as the foundation for the categorization system used in India, which is based on factors such as intended use, risk level, distribution

mode, and amount of bodily intrusion. Currently, in transition, the Indian regulatory system only needs import licenses for a limited number of product kinds. (27)

Table 1.1 Indian Medical Device Classification System

Class of Medical Device	Risk-involved	Examples
Class A	Low Risk	Alcohol swabs, Surgical dressings, etc.
Class B	Low Moderate Risk	Thermometer, BP monitoring device, etc.
Class C	Moderate-High Risk	Implants, Pacemaker, etc.
Class D	High Risk	Heart valve, Catheter, etc.

1.1.7 Top Medical devices present Globally

There might be 20,000 medical device businesses operating globally in 2022. It is observed that only 30 big corporations, representing close to 80% of worldwide sales, dominate the medical device market, having an annual revenue of close to USD 500 million. Many MSMEs split the remaining 20% of the medical device market's revenue. (28)

The top ten global medical device companies in 2022 are shown in the figure.

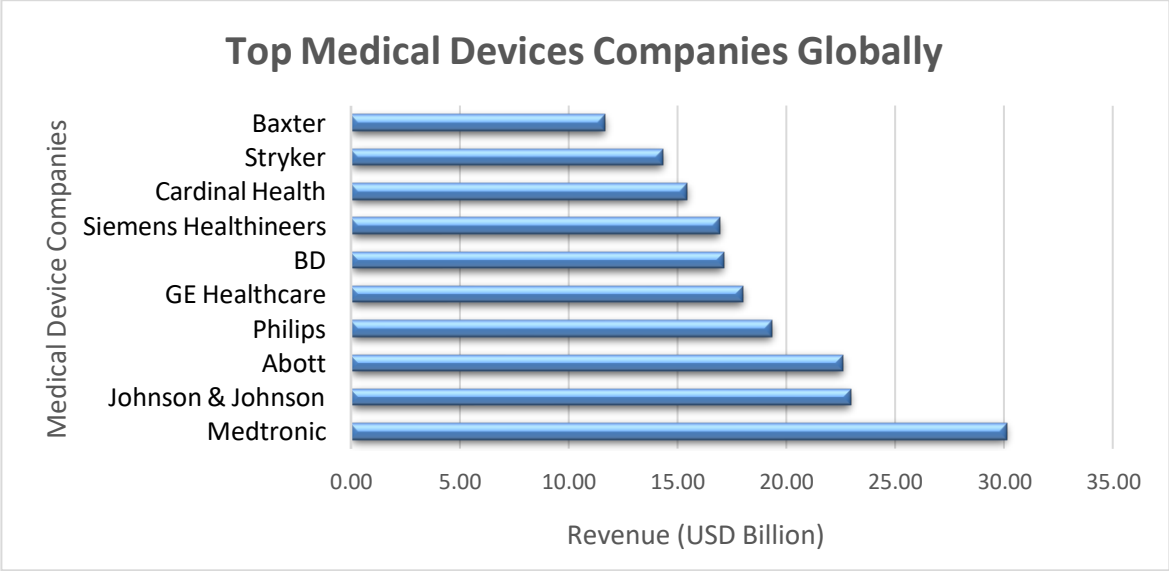

Figure 1.05 Top 10 Global Medical Devices and their Revenues (USD Billion)

1.2 Overview of Pharmacist's Medical Device Counselling

1.2.1 Meaning of Medical device counselling

Medical device counselling refers to providing medical device information verbally or in the form of writing to Doctors, Pharmacists, or Patients, on usage, precision, mechanical safety, and modifications.

The goal of excellent pharmacy practice, as stated in the World Health Organization (WHO) standards, is to "contribute to health improvement and to help patients with health problems to make the best use of their medicines." An essential service that has been linked to better clinical outcomes, quality of life, understanding of drugs and diseases, patient satisfaction, and lower use of health services is pharmacist-led counselling.

Medical gadgets that are available for direct consumer purchase are known as Over-the-Counter (OTC) products. In other words, a prescription may or may not be necessary to purchase these devices. OTC medical equipment examples include syringes, oximeters, dressings, etc. For any OTC Medical device, OTC Medical device counselling is quite necessary for pharmacists to provide proper guidelines to the patients. (29)

1.2.2 Overview on Pharmacists

Pharmacists are licensed medical professionals who disperse prescription drugs, monitor drug interactions, provide immunizations, and counsel patients on the effects and the use of prescription drugs and dietary supplements.

There are currently 17,00,000 chemists working in India. Professional experts in pharmaceuticals, chemists are. In addition to compounding and dispensing, they also provide patients and healthcare professionals with accurate, unbiased drug information. They give patients suggestions on how to deal with genuine drug-related problems and prevent others. It is exceedingly challenging for chemists to keep up with this quickly expanding and continually changing area of practice because medical devices are widely accessible in a range of practice situations (30).

1.2.3 Medical device counselling among pharmacists

When it comes to therapeutic difficulties, pharmacists make good counselors. Additionally, there is proof that counselling improves patients' clinical, humanistic, and financial results.

Community pharmacists have a tremendous opportunity to be the initial point of contact for patients looking for treatment for minor diseases in addition to distributing prescription and non-prescription drugs. Community pharmacists are playing a bigger and bigger part in public health by promoting healthy lifestyles. During contact between pharmacists and patients in the community, various non-medication-related concerns including food, device usage, exercise, and referrals may also be discussed. The neighbourhood environment has several benefits, including extended hours, accessibility, and familiarity.

Studies looking into community pharmacists' counselling techniques have found that their methods for gathering information before dispensing medication, identifying drug interactions, and creating counselling content are not up to par. The complicated nature of counselling in a community context may account for the subpar standards of community counselling practices.

Pharmacists must be knowledgeable about medical devices and should be able to explain their usage to patients. The patients will be given complete instructions on how to utilize the gadget, enabling them to become autonomous enough to do so. This is particularly crucial considering the growing concerns around ideas in bioethics such as wellness, independence, and healthcare which give consumers and customers greater rights and responsibilities when making decisions and taking care of their health.

Thus, more study is required to determine the best practices for various medical devices and patient demographics, as well as more standardized ways to counsel, train, and support pharmacists. (31, 32)

1.3 Aim

The aim of the study is to analyze the pharmacist's counselling practices related to medical devices.

1.4 Objectives

The objectives of this study are:

a. To identify the types of OTC Medical devices sold in a Pharmacy.
b. To determine the methods of counselling by Pharmacists.
c. To identify and analyze the common queries faced by the customers.
d. To determine the problems faced by the Pharmacist related to Medical device counselling.

Chapter 2: Review of Literature

Medical device counselling among pharmacists is an essential aspect of patient care, as they are often the primary source of engagement for patients seeking guidance about their medical devices Here is a brief review of some relevant literature on medical device counselling among pharmacists:

1. *Saini et al.* (2022) talked about the COVID-19 epidemic and the value of using medical devices at home, as well as how people's trust in these devices influences their utilization. The necessity for trustworthy and precise home medical equipment that people may use to monitor their health from the comfort of their homes has been brought to light, according to the authors, by the pandemic. The study paper is a review of the literature that examines several investigations on home-use medical devices that were carried out over the course of the 21-month COVID-19 pandemic.

   It was shown that people were more likely to use home medical equipment to keep an eye on vital signs like blood pressure, temperature, and oxygen saturation. Several aspects of in-home medical technology, such as the device's accuracy, dependability, price,accessibility, and usability, have an impact on people's trust in them. Devices with regulatory body certification and favorable user feedback were more likely to be trusted by consumers. The authors also pointed out that the COVID-19 pandemic saw a rise in the usage of home medical equipment because of hospital infections and the demand for remote medical treatment. However, the review discovered that using home medical devices presented few difficulties, including the requirement for appropriate training, language problems, and a lack of technical understanding. The evaluation also covered the difficulties healthcare providers encounter when implementing home medical devices, including a lack of standards, problems with interoperability, and the requirement for appropriate data protection and security safeguards. (33)

2. *Fathelrahman* (2021) investigated the usage of medical device guidance by community chemists in Saudi Arabia. A national survey of pharmacists was used to collect data from 850 community pharmacists for cross-functional research. The investigation showed most community chemists gave advise on the use of medical devices to their patients. However, only a few of the chemists were

aware of the local medical device restrictions. Most chemists said they felt comfortable consulting patients about medical equipment. Nonetheless, just half of the chemists reported having had medical device counselling training. Pharmacists who had obtained medical device counselling training were more likely to deliver adequate patient counselling. As a result, it was discovered that many community chemists in Saudi Arab. As a result, it was discovered that many community chemists in Saudi Arabia counselled their patients on the usage of medical equipment. However, there were gaps in chemists' understanding and counselling practices regarding medical devices. The study recommended that community chemists in Saudi Arabia obtain proper medical device counselling training to improve their knowledge and practices. (34)

3. Jiang S et al. (2021) looked on the efficacy of chemist interventions in avoiding medical device misuse in hospitalized patients. A comprehensive review and meta-analysis of 12 randomized controlled trials including a total of 2,849 patients were undertaken by the authors. Pharmacist interventions were found to be useful in lowering medical device-related adverse events and improving patient outcomes. The authors identified many forms of pharmacist interventions, including patient and healthcare provider education and training, medication reconciliation, and medication reviews.

These measures have been shown to be especially beneficial in avoiding catheter-associated urinary tract infections (CAUTIs) and central line-associated bloodstream infections (CLABSIs).

As a result, chemists help to reduce medical device misuse while also improving patient outcomes. Increased chemist participation in the treatment of hospitalized patients, according to the authors, could assist in reducing the frequency of medical device-related adverse events and improve patient safety.

Overall, the research sheds light on the efficacy of chemist interventions in avoiding medical device misuse in hospitalized patients. The findings indicate that pharmacist-led interventions can have a considerable influence on patient outcomes, emphasizing the importance of enhanced collaboration between chemists and healthcare practitioners to improve patient safety. (35)

4. Fathelrahman (2020) investigated pharmacy students' beliefs regarding their ability to counsel patients on medical devices. The authors performed a cross-sectional survey of 384 students from Saudi Arabian pharmacy colleges in their fourth, fifth, and sixth years to measure their knowledge, skills, and confidence in counselling patients regarding medical devices.

   According to the findings of the study, pharmacy students have poor knowledge and skills in counselling patients regarding medical devices. Several variables, according to the authors, contributed to this, including a lack of medical device training and education, limited access to information and resources, and a lack of confidence in their abilities.

   The research emphasizes the importance of better medical device counselling education and training for pharmacy students. According to the authors, introducing medical device education into pharmacy courses, providing students with resources and information, and expanding practical training opportunities could assist increase students' knowledge, abilities, and confidence.

   Overall, the study sheds light on pharmacy students' perceptions of their ability to counsel patients about medical devices. The findings indicate that more education and training in this area is needed, which could assist to enhance patient outcomes and ensure the safe and effective use of medical devices. (36)

5. Lavoie et al. (2018) wanted to see how pharmacist-led medical device advising affected patient outcomes and satisfaction in a community pharmacy context. The trial, which took place in Quebec, Canada, included 97 community pharmacies and 271 patients. The intervention group got pharmacist-led advice on how to utilize their medical devices, whereas the control group got routine care. Patient knowledge, device technique, and satisfaction were among the outcomes evaluated. When compared to the control group, patients who received pharmacist-led counselling had significantly higher knowledge ratings and improved skill scores.

   Furthermore, the intervention group reported higher levels of satisfaction with the therapy they got.. The study emphasizes the potential role of community chemists in improving patient outcomes through medical device advice. The authors proposed that including medical device counselling into standard

pharmacy practice could improve patient comprehension and usage of these devices, hence improving health outcomes. (37)

6. Bonds et al. (2014) investigated the prevalence and implications of medical device abuse among allergy and immunological illness patients. The researchers carried out a retrospective investigation on patients treated at a tertiary care allergy/immunology practice in the United States. The study included 61 individuals who used EpiPens and 31 who used Metered Dose Inhalers.
   According to the survey, a large proportion of individuals misused medical equipment such as inhalers and epinephrine auto-injectors. Patients who reported misusing these devices were more likely to have adverse events, such as hospitalizations and emergency room visits. Furthermore, patients who reported misusing these devices were less likely to have gotten sufficient training and teaching on their use.
   A conclusion was made that healthcare providers should prioritize education and training on the proper use of medical devices, particularly for patients with allergies and immune disorders who rely on these devices for life-saving treatments. They also recommend that healthcare providers assess patients' device use during routine visits and provide additional support as needed. (38)

7. Fox (2014) investigates the usage of personal medical devices and how they influence the experiences and self-management practices of people living with chronic illnesses. The author takes a materialist approach, emphasizing the importance of things and materiality in generating social interactions and power dynamics.
   The author demonstrates how, through a qualitative examination of interviews with people who use personal medical devices, these gadgets are more than just instruments for managing health; they also reflect a variety of social and cultural meanings. The study investigates the micropolitics of personal medical device use, including power, control, and surveillance issues. It was concluded that personal medical gadgets can both empower and constrain persons in their self-management practices, and that their use should be restricted, and their use must be comprehended within the context of social and cultural norms.

8. Puspitasari et al. (2010) investigated the perspectives of both pharmacists and consumers on prescription medicine advice in Australian community pharmacies. The study used a mixed-methods approach, with data obtained from 22 chemists and 157 consumers via questionnaires and interviews.

   While most chemists agree that prescription medication counselling is necessary, various challenges such as time restrictions, a lack of privacy in the pharmacy, and insufficient communication skills hinder them from offering good counselling. Consumers have favorable attitudes towards counselling and believe that it can help them better understand and use their medications. However, many customers claimed that they do not receive enough advice because of the same difficulties that chemists encounter. The study indicates that there is a need for more assistance for chemists to give prescription medication counselling, such as communication skills training and enhanced pharmacy design to provide more privacy. Furthermore, the study implies that improved consumer awareness of the importance of counselling and their rights to get it could benefit them. (40)

Chapter 3: Methodology

An online questionnaire was prepared, and research was conducted to find the Counselling practices related to Medical devices done by Indian Pharmacists and data were obtained based on Random and Convenience sampling techniques. The questionnaire was circulated for a period of 25 days from April 2023 to May 2023. The survey was for those Pharmacists who are working or own a community pharmacy shop, or a hospital pharmacy. It was ensured that only One response was collected from each Pharmacist.

A survey questionnaire is the main component of qualitative research. Respondents have finished a Microsoft Forms-based online survey. Through social media, chemists distributed the survey's link. A reminder was also sent to encourage community chemist engagement. 207 chemists in all volunteered to participate in the survey.

The Cross-sectional survey design consisted of 20 questions. The first 8 questions aim to find the general details about the Pharmacists, their background information, and their demographic details. The other questions included:

i. Their source of receiving information on Medical devices, 7 sources are given with an option to put other sources as well.
ii. Type of Medical Device available (13 components).
iii. Amount of counselling given over devices, using a Likert scale with five points and a possible range of 1–5 for each device.
iv. Various Methods of Counselling by Pharmacists., 6 methods using a Likert scale with five points and a possible range of 1–5 for each device.
v. The time taken for counselling, 4 options ranging from less than 1 minute to more than 5 minutes.
vi. The type of detailing shared with the customers/ consumers, using a Likert scale with five points and a possible range of 1–5 for each device.
vii. Level of confidence for counselling, 5 options from very satisfied to very dissatisfied.
viii. Queries faced by the customer with 6 options.
ix. Queries faced by customers on which devices. 13 devices using a Likert scale with

five points and a possible range of 1–5 for each device.

x. Barriers to counselling with 8 issues given as well other options are asked.

xi. Handling the unanswered queries by customers with 3 options and other options if any.

xii. And Suggestions, if any.

The Inclusion Criteria were Age, Gender, Location, Region, Experience, Qualifications, and Type of Pharmacy.

The Exclusion Criteria were Name and Language.

Scores on average ratings for all variables using 5-point Likert scale responses were calculated for each device (1=Never, 2=Rarely, 3=Sometimes, 4=Often, and 5=Always).

A final average score was produced for each of the questions, which revealed the counseling-related practices for each of the 13 medical devices (i.e., five factors on overall counselling practice scores).The scoreboard is mentioned in Table 3.1

Table 3.1: Scorecard on Mean response of the survey based on the Likert scale.

MEAN SCORE	**INDICATION**
More Than 4.00	Excellent
Between 3.51 – 4.00	Very Good
Between 3.01 To 3.50	Good
Between 2.01 To 3.00	Average
Between 1.50 To 2.00	Poor
Less Than 1.50	Very Poor

A brief description of the study and its goals was displayed in the description of the online survey to inform volunteers about the ethical considerations that have been put to protect their rights and interests. Informed consent was stated, which ensures that participants are aware of the study's purpose and are willing to participate on their own accord. It was

mentioned that personal data collected from participants is kept private and secure.

Finally, it was also stated that there will be no compromise on data shared. These ethical considerations have been taken seriously and have put in place all necessary measures to ensure that the rights of respondents are respected and protected.

Chapter 4: Results

4.1 Demographic Details and Background Information

A total of 207 Indian store chemists replied to the online poll. Most participants (54.10 %) belonged to the 26-35 age group. The majority (85.99%) were males. The majority had a bachelor's degree in pharmacy (52.65 %), belonged to the state of Maharashtra (35.74 %), and resided in Urban areas (74.87 %). On average, the participants had an experience of 6-10 years (31.40 %) and worked majorly in Local Pharmacy stores (65.70 %). Table 4.1 states the detail about the Participants and the demographic information.

Table 4.01: Demographic Details and Background Information of the Pharmacists

Parameter	**Options**	**Frequencies**
Gender	Male Female Others	178 (85.99 %) 27 (13.04 %) 02 (0.96 %)
Age	15-25 26-35 36-45 46-55 Above 55	47 (22.70 %) 112 (54.10 %) 28 (13.52 %) 19 (9.17 %) 01 (0.48 %)
Pharmacy Education	D. Pharm B. Pharm M. Pharm	93 (44.92 %) 109 (52.65 %) 05 (2.41 %)
Years of Experience	0-5	56 (27.05 %)

Table 4.01 continued.

	06-10 11-15 16-20 21-25 26-30 More than 30 years	65 (31.40 %) 35 (16.90 %) 31 (14.97 %) 13 (6.28 %) 06 (2.89 %) 01 (0.48 %)
Work State	Maharashtra Karnataka Telangana Gujrat Rajasthan Delhi	74 (35.74 %) 49 (23.67 %) 36 (17.39 %) 25 (12.07 %) 14 (6.76 %) 09 (4.34 %)
Work location	City Town Village	155 (74.87 %) 47 (22.70 %) 03 (1.44 %)
Type of Pharmacy	Local Pharmacy Franchise Pharmacy Hospital Pharmacy	136 (65.70 %) 28 (13.52 %) 43 (20.77 %)

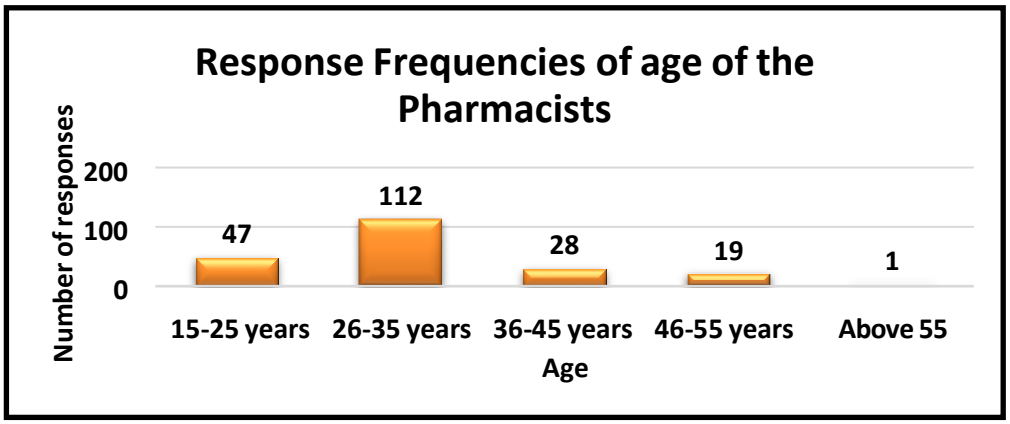

Figure 4.01 Clustered column graph for Age of the Respondents.

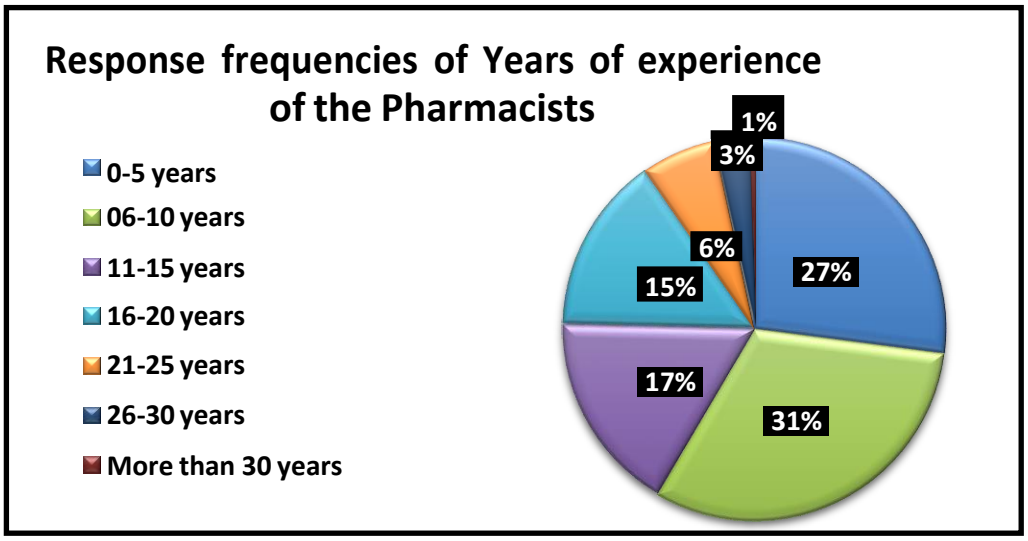

Figure 4.02 Pie Chart depicting Years of Experiences of the Respondents.

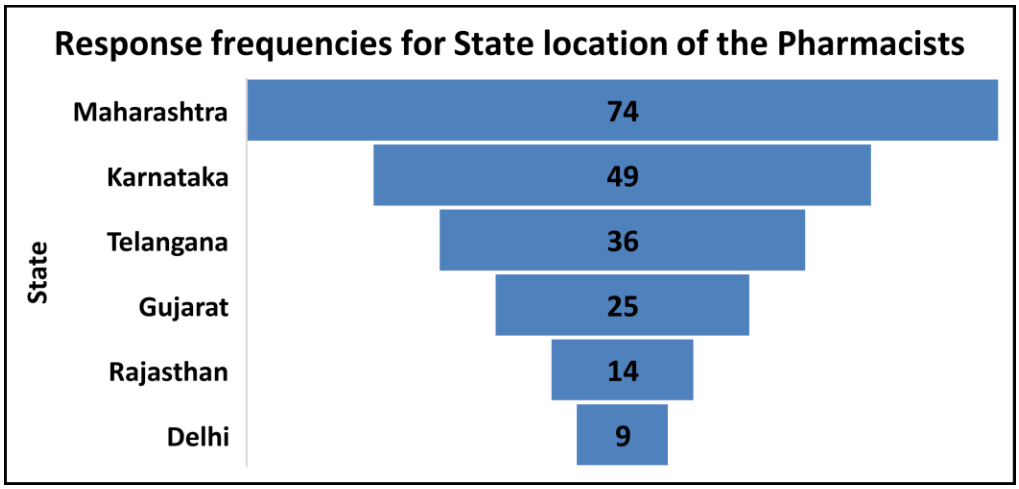

Figure 4.03 Funnel chart depicting State location of the Respondents.

4.2 Source of Information on Medical Devices

Table 4.2 shows the source of information on Medical Device knowledge that Pharmacists receive over the period. It was observed that Pharmacists receive major information through Medical Representatives (93.23%) and their Degree curriculum (70.04 %). Thus, these sources make Pharmacists aware of the trends in the Medical devices sector.

Table 4.02 Response Frequency for Source of Information

Source	Response Frequencies (Percentage)
Degree Curriculum	145 (70.04 %)
Medical Representatives	193 (93.23 %)
Medical Journal	37 (17.87 %)
Newspapers	60 (28.98 %)
Website	34 (16.42 %)
Social Media	61 (29.46 %)
Colleagues/ Relatives	42 (20.28 %)

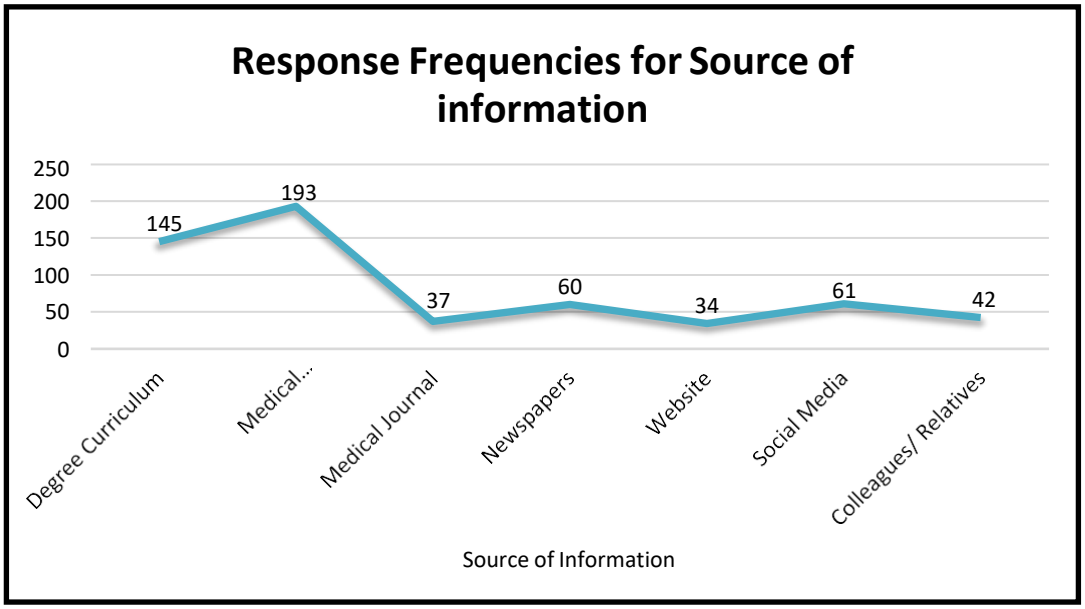

Figure 4.04 Line graph Source of Information Obtained by Respondents.

4.3 Medical device availability across the Pharmacies

Table 4.03 shows several types of Medical devices available at the Pharmacy stores where the respondents work. The top 5 available devices are First Aid boxes, Gloves, Test kits, Thermometers, (All 100%), and Injection/Syringes (99.03 %). Acupuncture Kits and Breast pumps received the lowest response with 59.90 % and 87.43 % respectively.

Table 4.03 Availability of Medical Devices in the Pharmacies

Name of the Device	**Response Frequencies (Percentage)**
Acupuncture Kit	124 (59.90 %)
Adult Diapers	192 (92.75 %)
Blood Glucometer	202 (97.58 %)
Breast Pump	181 (87.43 %)
First Aid Box	207 (100 %)
Gloves	207 (100 %)
Injection/ Syringe	205 (99.03 %)
Insulin Pen	182 (87.92 %)
Oximeter	190 (91.78 %)
Spacers/ Inhalers	188 (90.82 %)
Test Kits	207 (100 %)
Thermometer	207 (100 %)
Weighing Scales	195 (94.20 %)

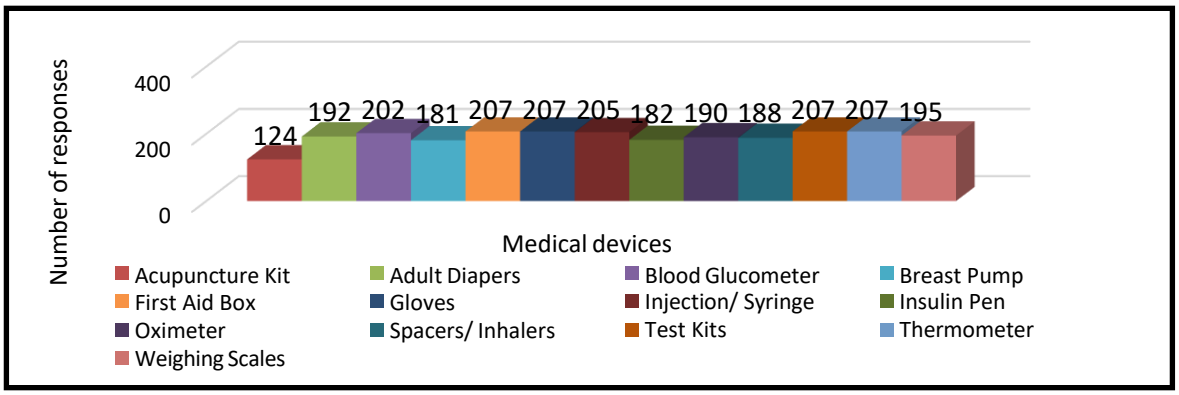

Figure 4.05 Column graph showing Availability of Medical Devices at the Pharmacies.**4.4**

Medical devices frequently bought by Customers.

Table 4.04 shows the data about the types of Medical Devices which are most frequently bought by customers. Based on the observations, Test Kits (Mean = 4.29), Adult diapers (Mean = 4.27), and Gloves (Mean =4.22) were the devices that were mostly bought by the customers. The Mean found is of the Likert scale value.

Table 4.04 Medical devices most frequently bought by patients.

Name of the Device	**Response Frequencies (Percentage)**					**Mean**
	Never (1)	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Always (5)**	
Acupuncture Kit	13 (6.28%)	85 (41.06%)	92 (44.44%)	12 (5.79%)	5 (2.41%)	2.57
Adult Diapers	2 (0.96%)	9 (4.34%)	23 (11.11%)	67 (32.36%)	106 (51.20%)	4.28
Blood Glucometer	6 (2.89%)	10 (4.83%)	88 (42.51%0	59 (28.50%)	44 (21.25%)	3.60
Breast Pump	8 (3.86%)	22 (10.62%)	75 (36.23%)	68 (32.85%)	34 (16.42%)	3.47
First Aid Box	3 (1.44%)	7 (3.38%)	26 (12.56%)	100 (48.30%)	71 (34.29%)	4.10
Gloves	1 (0.48%)	5 (2.41%)	28 (13.52%)	75 (36.23%)	98 (47.34%)	4.27
Injection/ Syringe	4 (1.93%)	13 (6.28%)	20 (9.66%)	66 (31.88%)	104 (50.24%)	4.22
Insulin Pen	0 (0%)	8 (3.86%)	17 (8.21%)	102 (49.27%)	80 (38.64%)	4.23
Oximeter	7 (3.38%)	4 (1.93%)	45 (21.73%)	79 (38.16%)	72 (34.78%)	3.99
Spacers/ Inhalers	5 (2.41%)	5 (2.41%)	81 (39.13%)	51 (24.63%)	65 (31.40%)	3.80

Table 4.04 continued

Test Kits	0 (0%)	2 (0.96%)	9 (4.34%)	121 (58.45%0	75 (36.23%)	4.29
Thermometer	2 (0.96%)	8 (3.86%)	17 (8.21%)	98 (47.34%)	82 (39.61%)	4.20
Weighing scales	10 (4.83%)	69 (33.33%)	32 (15.45%)	56 (27.05%)	40 (19.32%)	3.22

4.5 Devices needing most frequently Counselling for Customers

Table 4.05 shares the data about the devices and the frequent counselling needed by the customers by the pharmacists. Counselling is required to aid the receiver with the usage, tips, and precautions.

The Mean found is of the Likert scale value.

The top 3 devices are Insulin Pen (Mean = 4.45), Oximeter (Mean = 4.35), and Glucometer (Mean = 4.31). Gloves (Mean = 1.34) and Weighing scales (Mean = 1.39) have received less need for counselling.

Table 4.05 Devices most frequently requiring counselling reported by pharmacists

Name of the Device	**Response Frequencies (Percentage)**					**Mean**
	Never (1)	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Always (5)**	
Acupuncture Kit	77 (37.19%)	101 (48.79%)	16 (7.73%)	9 (4.34%)	4 (1.93%)	1.85
Adult Diapers	31 (14.97%)	57 (27.53%)	62 (29.95%)	35 (16.90%)	22 (10.62%)	2.80
Blood Glucometer	6 (2.89%)	12 (5.79%)	16 (7.73%)	50 (24.15%)	123 (59.42%)	4.31
Breast Pump	8 (3.86%)	20 (9.66%)	18 (8.69%)	99 (47.82%)	62 (29.95%)	3.90

Table 4.05 continued

First Aid Box	112 (54.10%)	68 (32.85%)	21 (10.14%)	4 (1.93%)	2 (0.96%)	1.62
Gloves	155 (74.87%)	37 (17.87%)	11 (5.31%)	4 (1.93%)	0 (0%)	1.34
Injection/ Syringe	31 (14.97%)	45 (21.73%)	77 (37.19%)	30 (14.49%)	24 (11.59%)	2.85
Insulin Pen	3 (1.44%)	5 (2.41%)	11 (5.31%)	63 (3.04%)	125 (60.38%)	4.45
Oximeter	4 (1.93%)	10 (4.83%)	14 (6.76%)	59 (28.50%)	120 (57.97%)	4.35
Test kits	20 (9.66%)	54 (26.08%)	64 (30.91%)	52 (25.12%)	17 (8.21%)	2.96
Thermometer	83 (40.09%)	94 (45.41%)	15 (7.24%)	8 (3.86%)	7 (3.38%)	1.85
Weighing scales	148 (71.49%)	42 (20.28%)	13 (6.28%)	3 (1.44%)	1 (0.48%)	1.39

4.6 Time taken for Counselling.

The time taken by the Pharmacists to counsel customers determines the amount of time spent to make customers understand the product. On average, Pharmacists take 1-3 minutes (54.58 %) to counsel the patients The OTC Medical devices are easier to use and do not take much time to get understood by the customers. Thus, Table 4.06 shows the data about the response frequencies.

Table 4.06 Time taken during Counselling.

Time period	**Response Frequencies (Percentage)**
Less than a minute	30 (14.49 %)
1-3 Minutes	113 (54.58 %)
3-5 Minutes	48 (23.18 %)
More than 5 minutes	16 (7.72 %)

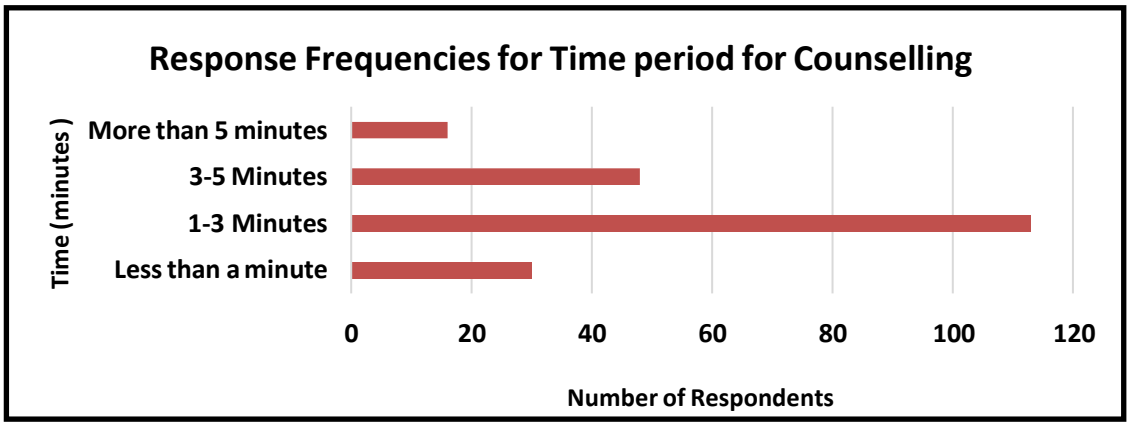

Figure 4.06 Clustered Bar graph showing Time taken to counsel the Customers.

4.7 Methods and Details shared during Counselling.

Table 4.07 below represents the ways by which Medical counselling is provided to patients.

The major response was given to Verbal (Mean = 4.04) and Demonstration (Mean = 3.52). The last response was given to Visual Aids (Mean = 1.88) The Mean found is of the Likert scale values.

Table 4.07 Forms of Medical Device Counselling.

Methods	**Response Frequencies (Percentage)**					**Mean**
	Never (1)	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Always (5)**	
Verbal	3 (1.44%)	12 (5.80%)	47 (22.70%)	56 (27.05%)	89 (42.99%)	4.04
Written	44 (21.25%)	29 (14.00%)	66 (31.88%)	48 (23.18%)	20 (9.66%)	2.85
Demonstration	16 (7.73%)	26 (12.56%)	39 (18.84%)	85 (41.06%)	41 (19.80%)	3.52
On Calls	50 (24.15%)	56 (27.05%)	43 (20.77%)	33 (15.94%)	25 (12.07%)	2.65
Visual Aids	82 (39.61%)	90 (43.47%)	18 (8.69%)	10 (4.83%)	7 (3.38%)	1.88

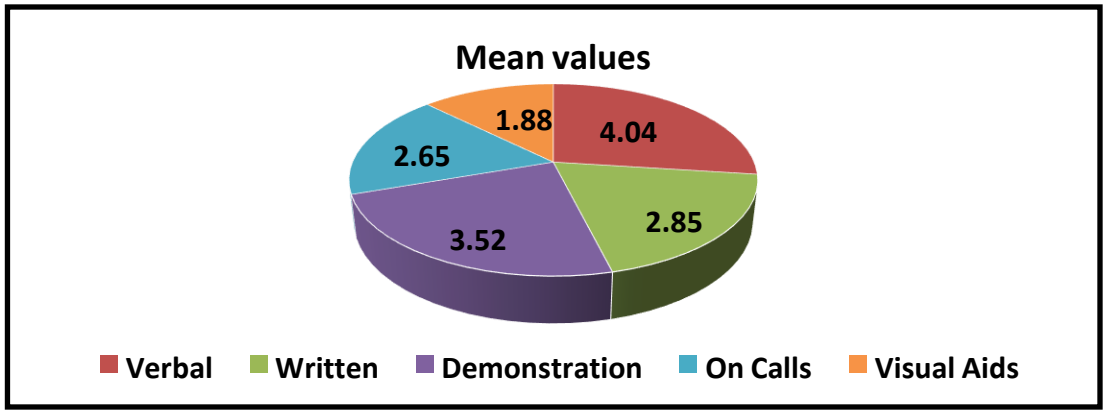

Figure 4.07 Pie Chart showing Mean values of various methods of Counselling.

Table 4.08 below shows the findings about the details of the Device that pharmacists share with the customers. It was observed that the details about the device usage tips (Mean = 4.12) and Precautions about the device (Mean = 4.00) were highly discussed by the Pharmacists. The last response was given to Side effects (Mean = 2.75)

The Mean found is of the Likert scale value.

Table 4.08 Types of Device details shared during Counselling.

Methods	**Response Frequencies (Percentage)**					**Mean**
	Never (1)	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Always (5)**	
Device Usage Tips	6 (2.89%)	11 (5.31%)	37 (17.87%)	51 (24.63%)	102 (49.27%)	4.12
Side Effects	49 (23.67%)	61 (29.46%)	21 (10.14%)	43 (20.77%)	33 (15.94%)	2.75
Recommending the right device	19 (9.17%)	28 (13.52%)	36 (17.39%)	65 (31.40%)	59 (28.50%)	3.56
Giving overall information about the device	22 (10.62%)	34 (16.42%)	58 (28.01%)	46 (22.22%)	47 (22.70%)	3.30
Precautions about the device	21 (10.14%)	11 (5.31%)	12 (5.79%)	64 (30.91%)	99 (47.82%)	4.00

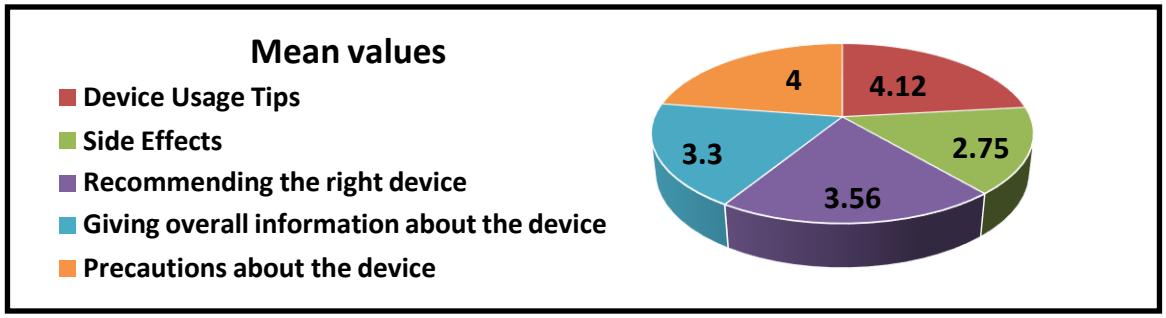

Figure 4.08 Mean values of types of details shared during counselling.

4.8 Queries during Medical Device Counselling

Table 4.09 shows the Queries faced by the customer about a particular Medical device from a Pharmacists perspective. It is seen that most customers have queries regarding Precautions 182 (87.92 %) followed by knowing the Warranty period 138 (66.66 %) and understanding the Usage and Maintenance 130 (62.80 %) respectively.

Table 4.09 Various Customer queries while purchasing devices.

Customer queries	Response frequencies (Percentage)
Usage and Maintenance	130 (62.80 %)
Precautions	182 (87.92 %)
Return policy	126 (60.86 %)
Warranty	138 (66.66 %)
Alternative devices or brands	104 (50.24 %)
Dispose	51 (24.63 %)

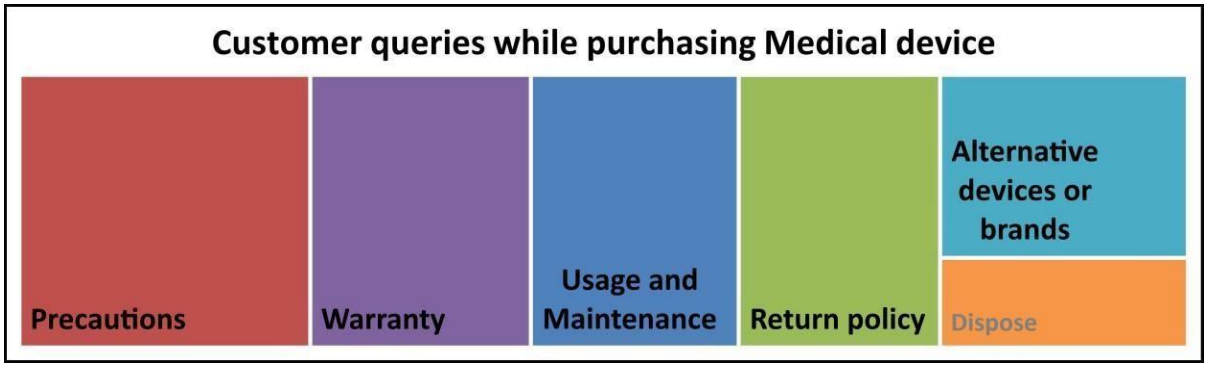

Figure 4.09 Tree Map showing Customer queries while purchasing Medical devices.

Table 4.10 shows the Barriers faced by Pharmacists during Medical device counselling. Through the survey, it can be reported that Customer needs Doctor validation before buying a Medical device from Pharmacists 110 (53.14 %). Many pharmacists showed that they do not face any barriers and can counsel the patients with ease 105 (50.72 %). Time limitation was also observed as a big reason as a barrier to counselling 102 (49.27 %).

Table 4.10 Barriers to Medical Device Counselling

Barriers	**Response frequencies (Percentage)**
No issues faced	105 (50.72 %)
Time limitation	102 (49.27 %)
The customer is not willing to listen	78 (37.68 %)
The customer needs the doctor's validation	110 (53.14 %)
Lack of Knowledge	51 (24.63%)
You are shy	50 (24.15 %)
Less number of Pharmacists	25 (12.07 %)
Language barrier	22 (10.62 %)

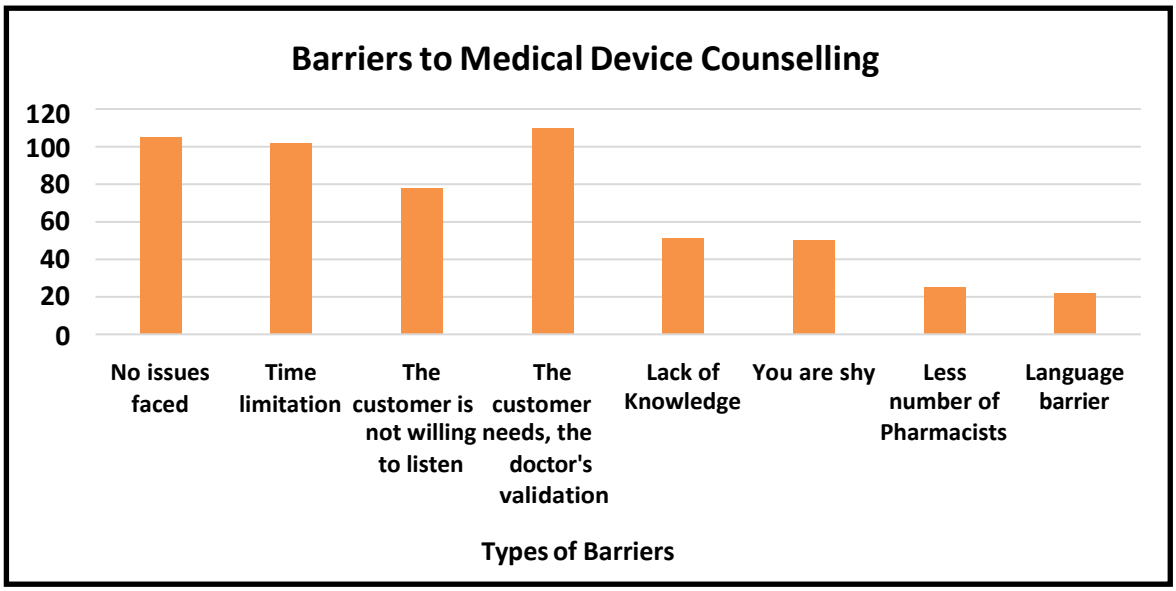

Figure 4.10 Clustered bar graph showing various barriers to Medical device counselling.

Table 4.11 shows the data about the ways by which Pharmacists tackle customer queries that they do not know. It is seen that most Pharmacists are willing to look for the information by themselves and then answer customers (52.17 %). A sizeable number of Pharmacists are not hesitant to refer other Pharmacists to tackle unknown customer queries (43.96 %).

4.11 Ways of tackling unknown Customer Queries

Tackling the queries	**Response frequencies (Percentage)**
Refer to another Pharmacist	91 (43.96 %)
Refer the customer to another healthcare professional (e.g., Doctor, Nurse)	08 (3.86 %)
Look up the information and get back to the customer	108 (52.17 %)

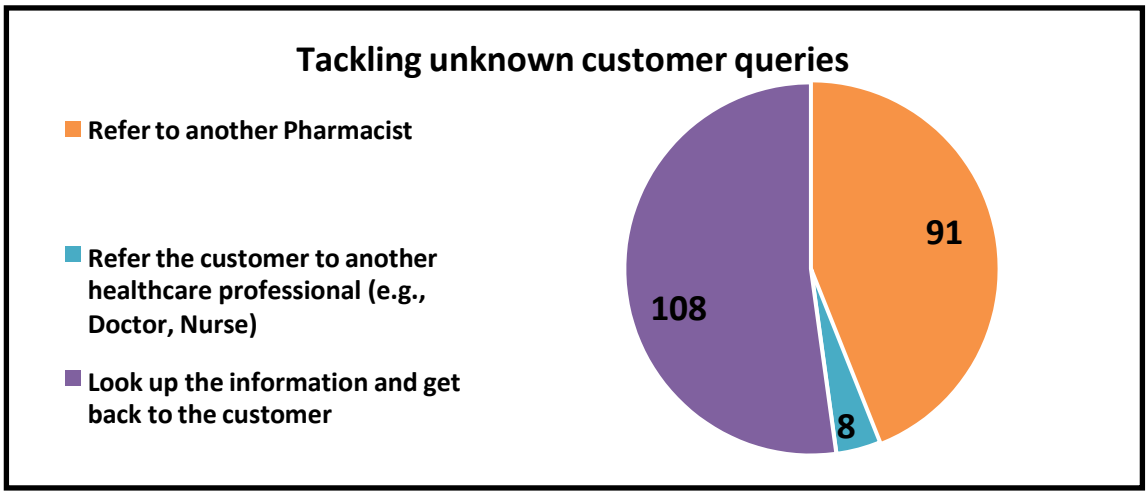

Figure 4.11 Pie charts showing Methods of tackling unknown customer queries.

4.9 Level of Confidence during Counselling

Table 4.12 below shows the data on the question which aims to find how confident a Pharmacist feels while solving customers' queries. Many respondents feel that they are very satisfied with the level of confidence they have (43.96 %). Only 1 person 0.48%) in this survey seems to be very dissatisfied with their way of their work.

Table 4.12 Confidence level in answering Customer queries.

Level	Response frequencies (Percentage)
Very satisfied	135 (43.96 %)
Somewhat satisfied	49 (23.67 %)
Neutral	18 (8.70 %)
Somewhat dissatisfied	04 (1.93 %)
Very dissatisfied	01 (0.48 %)

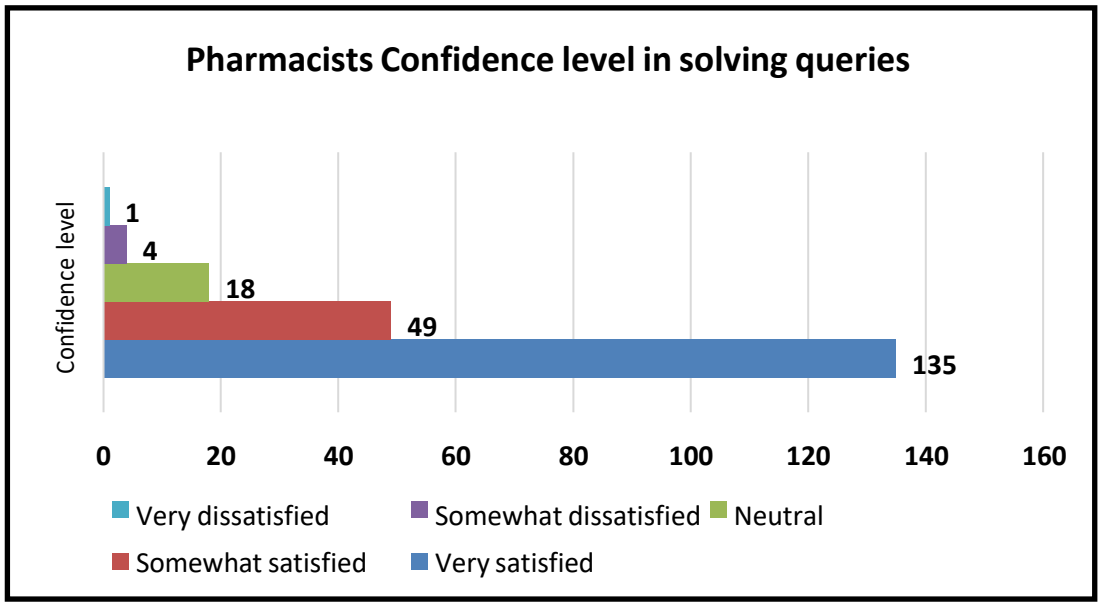

Figure 4.12 Pharmacist's Confidence Level in solving queries.

Chapter 5: Discussion

The outcome of the questionnaire survey has provided insights into the Medical device counselling by Pharmacists to patients. The chapter reflects the research process. The results shall be compared with other studies to show the relevance of the survey. The strengths and limitations of this research will be discussed along with the overall findings and interpretations.

Community pharmacists have a significant impact on their societies globally as providers of pharmaceutical and health care. There is a crucial new function that community chemists everywhere are expected to do effectively: serving the community needs to be related to medical devices. Clients and patients visit neighbourhood pharmacies and ask for a range of pharmaceuticals, cosmetics, and medical equipment without a prescription. Community pharmacists must exercise control over this to minimize risks from overuse and irrational usage and to guarantee that the intended effects are realized. This calls for pharmacists to be prepared with the necessary knowledge and abilities as well as willing to advise patients about such items.

Pharmacists have a special set of skills that they use in helping patients take care of their medications for the best results. Through formulary management, chemists are frequently in charge of determining and reviewing the proper use of medications based on their efficacy, safety, and cost-effectiveness.

The survey revealed a lot about counselling practice by pharmacists. The number of female respondents was less as compared to the male counterparts indicating that female pharmacists are either part of the academics or in managing organizations. A couple of responses stated others as their genders which suggests gender inclusivity. Many pharmacists in the stores belong to the middle age group having a decent experience in practice. With respect to education, there is a high number of both B. Pharma and D. Pharma students.

With respect to the source of information on the devices, the degree curriculum and the Medical representatives of a particular company play a significant role. It was seen that Pharmacists do not go through the website majorly to check new products or trends in the

Industry. Even if a particular home care medical device is not available, they should know about it.

Most of the home medical devices were available at the pharmacist's store with more than 85% responses for each device except for the Acupuncture kits. The response needs to be more than 95 % but it can be due to less availability of devices due to the remote location of the pharmacies.

Customers buy medical devices based on their needs. For this research, the Likert scale was used, and a mean value was taken out. The responses range was based on Average to Excellent. Quite simple devices such as test kits and gloves received excellent responses, suggesting a huge audience and high usage. Devices such as Oximeters, Glucometers, and Spacers had responses of Good and Very good which indicates that these devices are not bought that frequently but the demand for them is increasing.

Insulin Pen, Oximeter, and Glucometer needed the highest amount of counselling by pharmacists and received the highest mean score. These devices provide advanced aid to the body as compared to other home medical devices. Gloves and weighing are easy to use and for understanding and thus they receive less amount for counselling. It can be stated that the device which is bought more need not require a prominent level of counselling.
It is proved in various research papers that Pharmacists led educational interventions results in medication errors.

On average, Pharmacists take 1-3 minutes to counsel their customers which means that the counselling done is quite precise which further will help patients to easily understand the device without any stress or confusion.

Many Pharmacists believe in Verbal counselling for patients. The second most popular option was a demonstration. This will keep the customer engaged and it will be easier for them to understand the product. Another observation was about the details shared about the device. Pharmacists majorly share details about the device usage tips followed by precautions. If the patients have other queries they address them accordingly.

Customers will always face some queries regarding medical devices. The major query is about Precautions followed by Warranty period and Usage and maintenance. Indirectly, the value of money is observed here.

Pharmacists also have their own set of barriers to counselling, and they might have to deal with them on an everyday basis. The biggest challenge is Patients need a doctor's validation before trying the medical device. This can also mean that Customers may not trust Pharmacists and their suggestions, and they are not willing to try any device just because the pharmacists suggested it. Thus, it can be also stated that Customers are not willing to try out other brands or any alternatives without the approval from their Doctors. Many Pharmacists claimed that they did not face any issues while counselling. A section of Pharmacists believed that there is insufficient time to counsel the Customers.
This supports the finding shown by Muhammad Kamran Rasheed and others. (41)

At one point, Pharmacists will face queries that they do not know how to answer them. Majority of the Pharmacists believe in looking up the answers there and then counselling the patients. This shows that they have the attitude to learn and be aware of the latest development in the healthcare system.

Overall, it was seen that more than half of the respondents are satisfied with the type of knowledge and training that they have received. They are confident enough to counsel the Customer and solve their queries.

This research paper aims to understand the perception of Pharmacists and their counselling practices toward Customers. Generally, Pharmacists deal with drugs. However, Pharmacists need to know about Medical devices and their trends across the industry. The qualitative research study also sees the way Pharmacists deal with the query, their barriers, and how they solve them. This also helps to find what type of medical devices are available at a Pharmacy store, and which are the devices that need the most amount of counselling. The benefit of doing the survey online helped in reaching the survey across many states of the country. According to Schommer and Wiederholt, chemists in various practice settings and leadership roles reported varying counselling-related obstacles and enablers. (42)

However, there are certain limitations in this study. There are a smaller number of participants in the survey as compared to the total population of Indian pharmacists. There may also be a bias in selecting the options. Thus, it cannot be proved that Pharmacists are confident enough with their skill sets. The survey should have reached all the pharmacists. The form of the survey was online and not offline. An offline survey helps in better understanding the Pharmacists' perspective as direct interaction takes place.

A systematic review (43) by Basak et al. determined that community pharmacists' healthcare services were negligible and required modification to satisfy the evolving needs of modern medicine users.

Thus, Pharmacists should be updated about the Medical device industry, its trends, and awareness and should also ensure that Customers receive the best counselling details.

Chapter 6: Conclusion

The research aimed to identify the perspective of the Pharmacists and the way they provide Medical counselling to the customers. Based on a qualitative analysis of Pharmacist's perceptions in response to the survey, it can be concluded that Pharmacists all over India counsel their patients about home care medical devices. The results indicate that Pharmacists are eager to counsel their Customers and are willing to be aware of new trends.

The current Research aimed to identify the type of home care medical devices available, the counselling practices by the Pharmacists, their way of dealing with customer queries, and how the queries are being solved.

This research has analyzed the methods by which counselling of medical devices by Pharmacists. It was found that the devices which are frequently bought do not need to be the ones that need counselling. Taking the example of Gloves, the rate of buying gloves is high but one does not need counselling on how to use the gloves and how to maintain them. Another analysis of representation by a smaller number of female participants should be increased in the Pharmacy stores. Pharmacists overall seem to be confident about the training that they have received but, a certain section does not seem to be that satisfied with the counselling practice.

On the other hand, it would be anticipated that the characteristics of various industries and practice contexts would have an impact on how differently pharmacist’s practice.

Evidence indicates that the efficacy of educational medical device treatments varied according to the practice setting, with outpatient clinics demonstrating the best outcomes (44). Contrary to the preceding statistics, however, there were no discernible distinctions in the medical devices that patients requested, the devices that required the most counselling, and the devices that were most supplied among our chemists by sector.

The benefits of expert medical device counselling for patients and clients are many. The degree to which patients find their devices to be convenient and satisfying affects how well they adhere to their pharmaceutical therapy, which in turn affects their health outcomes and

costs. (45) According to Arora et al., "Proper patient education on proper usage may not only improve control of the disease's symptoms but may also allow dose reduction over time." (46)

According to the study, counselling techniques varied, but they were usually seen as acceptable across a variety of devices. The findings demonstrate how devices are easily accessible on the market and how chemists cater to patients' needs. Findings indicate that because patient inquiries are frequent, chemists should maintain current knowledge of how to use medical devices correctly.

The current study found that self-reported counselling practices connected to medical devices were satisfactory to excellent. Future studies must be more thorough if they are to assess chemists' actual performance in this field. Government programs and pharmacy instructors should focus on improving the knowledge and abilities of pharmacists to improve their contribution to medical device supportive services.

Thus, Medical device counselling is an important phenomenon that should be done by the Pharmacists. In the future, this research should be taken up at a national level so that the Government of India can understand the perception of the Pharmacists, their needs and wants, and Customer queries. If this survey is done on the ground level, then there will be a better understanding of this research which in turn will lead to a better healthcare pyramid.

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Annexures

Online Questionnaire

Medical Device related Counselling practices amongst Store Pharmacists in India.

Hello Everyone, I am a student of IIHMR University. I request your participation in this survey that is a crucial part of my Dissertation research. **The survey is for Pharmacists who are working or own a Pharmacy shop or Hospital Pharmacy.**
Your responses will be kept confidential and anonymous. Participation is voluntary.
I kindly ask you to please take the time to fill out my survey and share it with anyone else who may be interested. Your help is appreciated in my academic endeavours.
Thank you in advance for your support, and please feel free to contact me if you have any questions or concerns.

1. Name

Enter your answer.

2. Gender

- ○ Male
- ○ Female
- ○ Others

3. Age

- ○ 15-25
- ○ 26-35
- ○ 36-45
- ○ 46-55
- ○ Above 55

4. Pharmacy Education

- ○ D. Pharm
- ○ B. Pharm
- ○ M. Pharm

5. Years of Experience

- ○ 0-5
- ○ 6-10
- ○ 11-15

- ○ 16-20
- ○ 21-25
- ○ 26-30 Years
- ○ More than 30 Years

6. Your Location (State)

Enter your answer.

7. where do you work?

- ○ City
- ○ Town
- ○ Village

8. What type of Pharmacy do you work in?

- ○ Local Pharmacy
- ○ Franchise Pharmacy
- ○ Hospital Pharmacy

9. From where you get Information about Medical devices?

Required to answer. Multiple choice.

- ϒ Degree Curriculum
- ϒ Medical Representatives
- ϒ Medical Journal
- ϒ Newspapers
- ϒ Website
- ϒ Social Media
- ϒ Colleagues/ Relatives

10. Which type of Medical Devices are available at your Pharmacy shop?

- ϒ Acupuncture kit
- ϒ Adult Diapers
- ϒ Blood Glucometer
- ϒ Breast Pump
- ϒ First Aid Box
- ϒ Gloves
- ϒ Injections/ Syringes
- ϒ Insulin Pens
- ϒ Oximeter
- ϒ Spacers/ Inhalers
- ϒ Test Kits
- ϒ Thermometer
- ϒ Weighing scales

11. On a scale of 1 to 5, Customers buy which medical device *

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Always (5)
Acupuncture Kit	○	○	○	○	○
Adult Diapers	○	○	○	○	○
Blood Glucometer	○	○	○	○	○
Breast Pumps	○	○	○	○	○
First Aid Box	○	○	○	○	○
Gloves	○	○	○	○	○
Injection/ Syringe	○	○	○	○	○
Insulin Pens	○	○	○	○	○
Oxymeter	○	○	○	○	○
Spacer/ Inhalers	○	○	○	○	○
Test Kits	○	○	○	○	○
Thermometer	○	○	○	○	○
Weighing Scales	○	○	○	○	○
Others	○	○	○	○	○

12. On a scale of 1 to 5, how much counselling do you give to the consumers/customers on the following Medical devices? *

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Always (5)
Acupuncture Kit	○	○	○	○	○
Adult Diapers	○	○	○	○	○
Blood Glucometer	○	○	○	○	○
Breast Pump	○	○	○	○	○
First Aid Box	○	○	○	○	○
Gloves	○	○	○	○	○
Injection/ Syringe	○	○	○	○	○
Insulin Pens	○	○	○	○	○
Oxymeter	○	○	○	○	○
Spacers/ Inhalers	○	○	○	○	○
Test Kits	○	○	○	○	○
Thermometer	○	○	○	○	○
Weighing Scales	○	○	○	○	○
Other	○	○	○	○	○

13. On a scale of 1 to 5, How do you Counsel your Patients about Medical Devices? *

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Always (5)
Verbal	○	○	○	○	○
Written	○	○	○	○	○
Demonstrations	○	○	○	○	○
On Calls	○	○	○	○	○
Visual Aids	○	○	○	○	○

14.How much time do you typically spend counselling a patient about the device?

- ○ Less than 1 minute
- ○ 1 - 3 minutes
- ○ 3 - 5 minutes
- ○ More than 5 minutes

15. On a scale of 1 to 5, What type of Medical device details do you share with your Customers/ Consumers? *

	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Always (5)
Device Usage Tips	○	○	○	○	○
Side Effects	○	○	○	○	○
Recommending the right device	○	○	○	○	○
Giving overall information about the device	○	○	○	○	○
Precautions about the device	○	○	○	○	○

16. How satisfied are you with the level of confidence on training and education provided to you on how to address customer queries related to medications or medical devices?

- ○ Very satisfied
- ○ Somewhat satisfied
- ○ Neutral
- ○ Somewhat dissatisfied
- ○ Very dissatisfied

17. What are the queries faced by the customers when buying a medical device from pharmacies? Required to answer. Multiple choice.

- ☐ Usage and Maintenance
- ☐ Precautions
- ☐ Return policy
- ☐ Warranty
- ☐ Alternative device or brands
- ☐ Dispose

18. What issues do you face while explaining the device to patients?

- ☐ No Issues Faced
- ☐ Time limitation
- ☐ Customer is not willing to listen
- ☐ Customer needs doctor validation
- ☐ Lack of Knowledge
- ☐ You are shy
- ☐ Less number of Pharmacists
- ☐ Language barrier

19. How do you typically handle a customer's query that you are not able to answer?

- ☐ Refer to another Pharmacist
- ☐ Refer the customer to another healthcare professional (e.g., doctor, nurse)
- ☐ Look up the information and get back to the customer

20. Suggestions (if any).

Enter your answer.