

Analyzing the Medical Devices related Counselling practices among Indian Pharmacists



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1. Introduction

❖ What are Medical devices?

Medical Devices are any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination to prevent, diagnose, or treat disease or other medical conditions.

E.g. - Thermometer, Pacemaker, Syringes, Ultrasound, etc.

- The first Historical instance of Medical devices was seen in Baluchistan around 700 BC. It was also seen in Egypt and Romans.
- Physician Al-Zahrawia authored a book, Kitab al-Tasrif in the 10th century, stating several medical instruments used conduct operations in that era.



Medical devices mentioned in Kitab al- Tasrif

❖ Regulatory bodies for Medical Devices

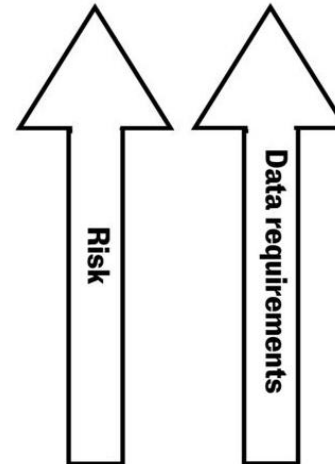
- In USA, USFDA governs the Medical device.
- EMA governs the Medical devices across European countries.
- IMDRF promotes the global convergence of regulatory standards & practices
- In India, CDSCO has been designated as primary regulatory authority for the import, sale, and production of medical devices.



❖ Medical Device

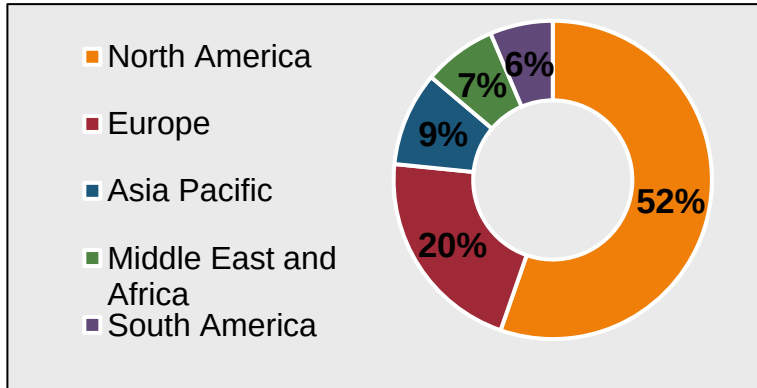
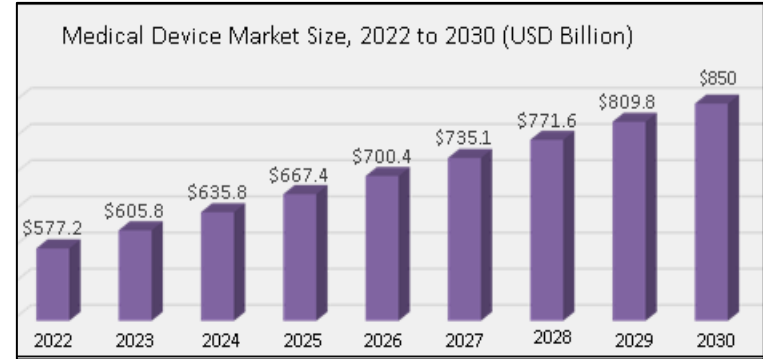
Classification
across the Globe

EU	USA	India
Class III	Class III	Class D
Class IIb	Class II	Class C
Class IIa		Class B
Class I (1s, 1r, 1m)	Class I	Class A



❖ Global Medical Device Industry Market

- The Industry generated USD 550 billion in worldwide sales in 2022
- CAGR of 5.5% in 2030 to reach USD 850 billion in sales.
- Factors for growth are innovation and modern technology
Creation of New devices, Systematic regulations,
More R&D activities, Ageing population, Global
Incident Diseases, etc.
- Trends seen: Telemedicine, AI, Robotics, Digital
health, Increase in Diagnostics, etc.
- The industry includes hospitals, ambulatory surgical centers,
clinics, diagnostics centers, etc.



Regional distribution of Medical devices

- North America accounts for highest usage of Medical device followed by European Union.
- This proves Reliable infrastructure, advanced technology, portable equipment, etc.
- Increase in Diabetes, Orthopaedic and Ophthalmic disease will contribute to more usage of Medical devices globally.

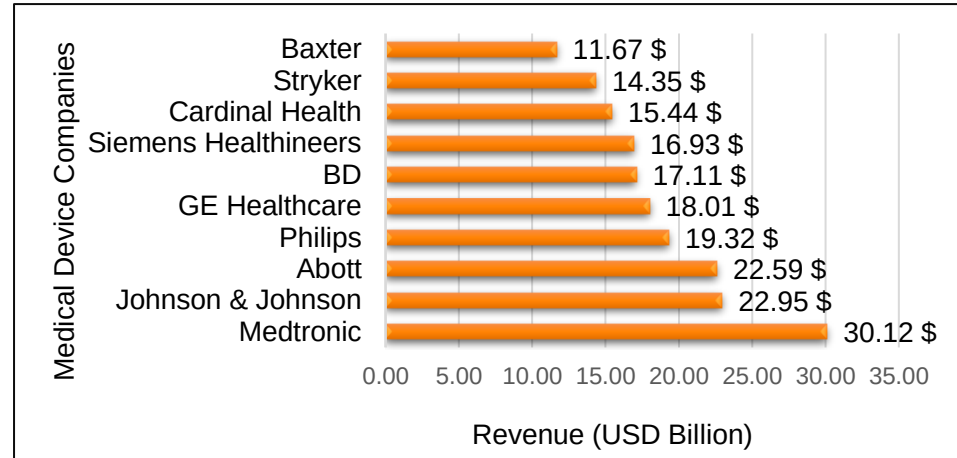
❖ Indian Medical Device Market

- Current worth \$12 billion, CAGR – 15%
- Accounts for 1.5% of the worldwide medical device market.
- Potential to reach \$ 50 billion by 2030.
- This is due to rising medical technology demand, FDI influx, and export prospects.
- Increase in Local manufacturing, New Medical device Tech parks, New policies.
- Highest revenue is generated from the Diagnostic market (30 %) of the Indian Medical Device.



❖ Top Medical devices present Globally

- Top 30 Medical device make up to 80% Global Sales.
- Top 10 Medical devices in 2022 along with their Revenue are shown in the graph.



Top 10 Global Medical Devices 2022 and their Revenue (USD Billion)

❖ Medical Device Counselling by Pharmacists



- Medical device counselling refers to providing Medical device information verbally or in the form of writing by Doctors, Pharmacists to Patients, on usage, precision, mechanical safety, and modifications.
- Counselling helps in contributing to health improvement and to help patients with health problems to make the best use of their medicines.
- Medical devices that are available for direct consumer purchase are known as Over-the-Counter (OTC) products.
- OTC Medical equipment examples include Syringes, Oximeters, Dressings, etc.
- Pharmacists must be knowledgeable about Medical devices and should be able to explain their usage to patients.
- Counselling gives Consumers and Customers greater rights and responsibilities when making decisions and taking care of their health.

2. Aim & Objectives

Aim:

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



Objective:

- 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.

3. Methodology

- The research done is a **Qualitative** research.
- An **Online** Questionnaire was prepared, based on **Random and Convenience sampling** techniques.
- The survey was for those Pharmacists who worked in a **Local, Franchise or Hospital Pharmacies**.
- The **Cross functional study** comprised of **20 questions**. **207 Pharmacists** in all volunteered to participate in the survey.
- The **Inclusion** Criteria were **Age, Gender, Location, Region, Experience, Qualifications**, and **Type of Pharmacy**.
- The **Exclusion** Criteria were **Name** and **Language**.

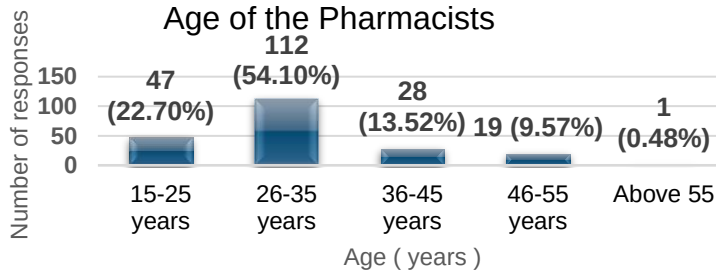
- An Average score based out of Likert Scale was determined for each devices

Mean Score	Indication
More than 4.00	Excellent
Between 3.51 to 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

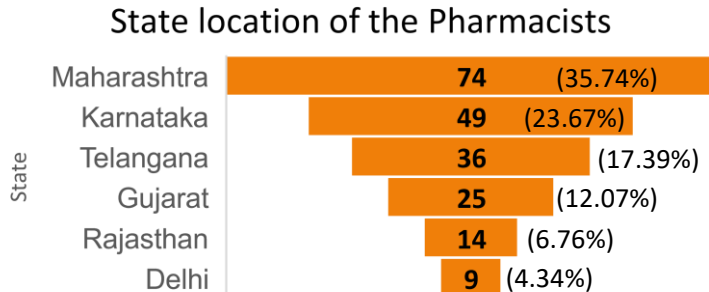
- All the Ethical considerations, Online consent was mentioned in the form.
- Participation was done willingly with surety of data to be kept private.

4. Results

1. Demographic Information



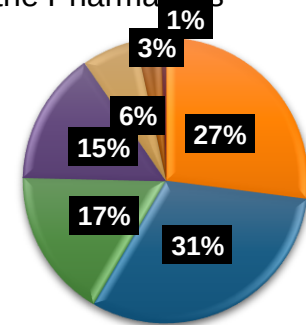
- With respect to Work location, City 155 (74.87 %), Town 47 (22.70 %), Village 03 (1.44 %)



- With respect to Gender, Male 178 (85.99%), Female 27 (13.04%), Others 2 (0.96%)
- With respect to Qualification, D. Pharm 93 (44.92%), B. Pharm 109 (52.65 %), M. Pharm 5 (2.41 %)

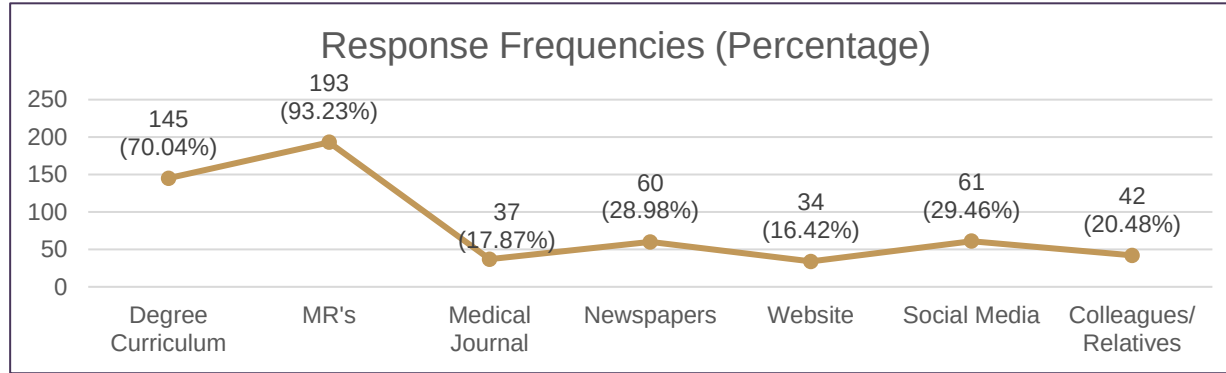
Years of experience of the Pharmacists

- 0-5 years
- 06-10 years
- 11-15 years
- 16-20 years
- 21-25 years
- 26-30 years
- More than 30 years



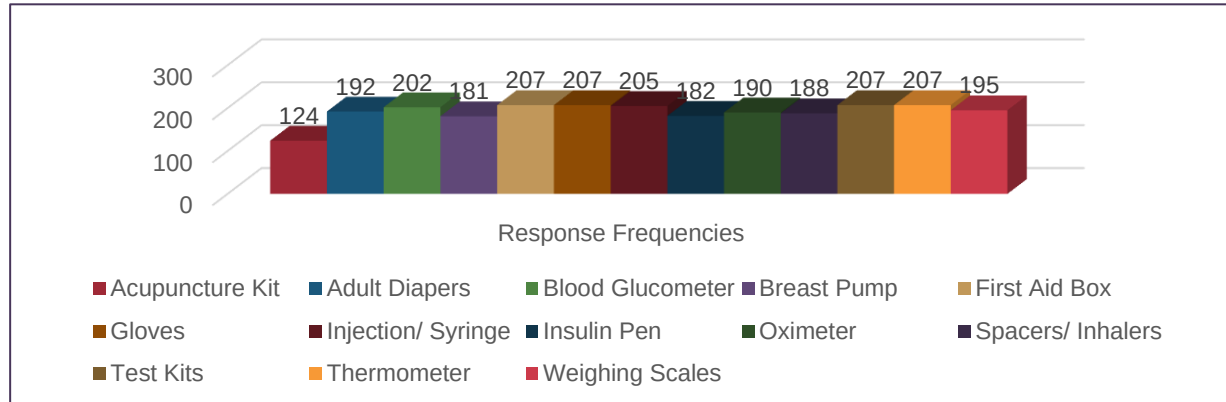
- With respect to the type of Pharmacy, Local Pharmacy 136 (65.70 %), Franchise Pharmacy 28 (13.52 %), Hospital Pharmacy 43 (20.77 %)

2. Source of Information on Medical Devices



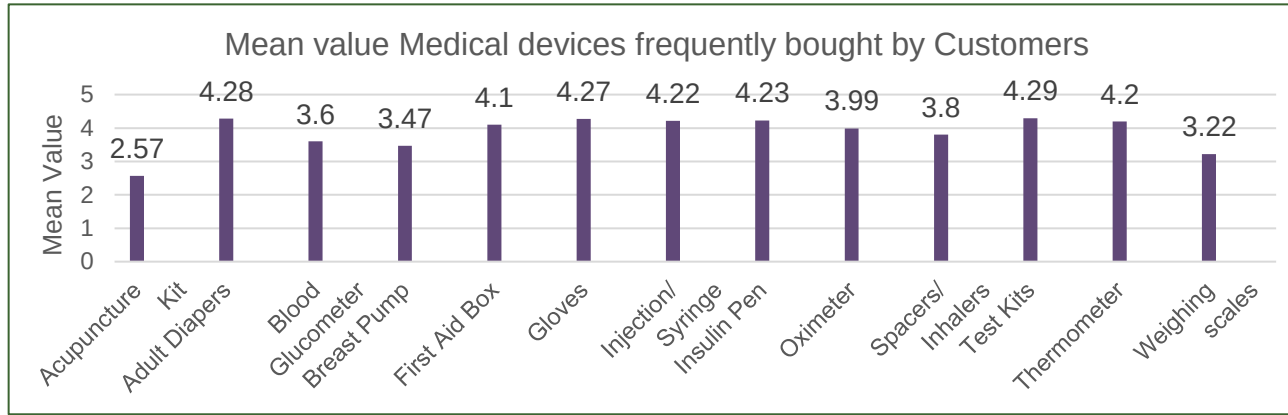
- Pharmacists receive major information through Medical Representatives (93.23%) and their Degree curriculum (70.04 %).
- Least response is given to Website (16.42%).

3. Medical device availability across the Pharmacies



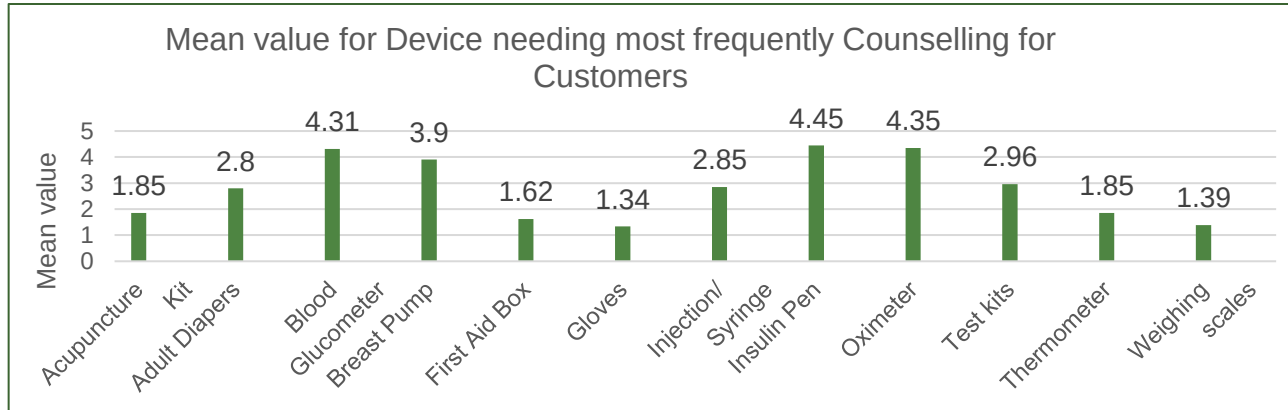
- The top 5 available devices are First Aid boxes, Gloves, Test kits, Thermometers, (All 100%), and Injection/Syringes (99.03 %).
- Acupuncture Kits and Breast pumps received the lowest response with 59.90 % and 87.43 % respectively

4. Medical devices frequently bought by Customers



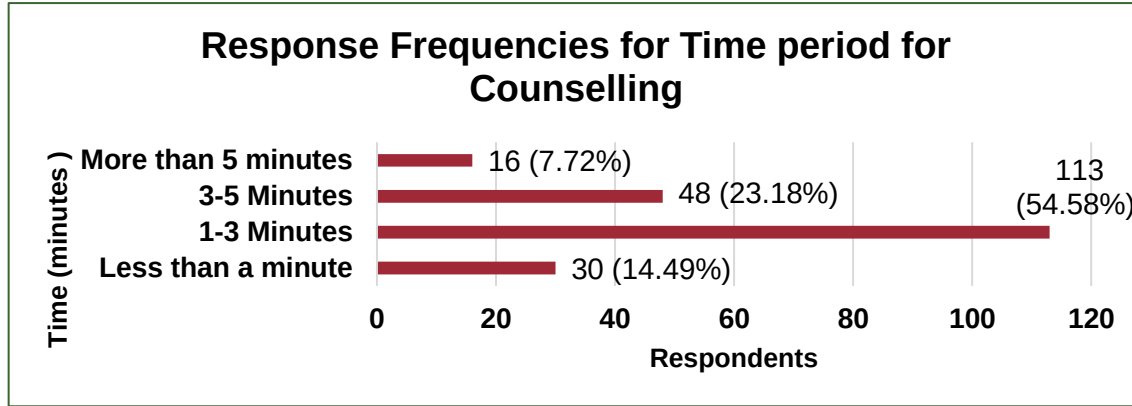
- Test Kits (Mean = 4.29), Adult diapers (Mean = 4.27), and Gloves (Mean = 4.22) were the devices that were mostly bought by the customers.
- Weighing scales (Mean = 3.22) and Acupuncture Kit (Mean = 2.57) were least bought by the customers.

5. Devices needing most frequently Counselling for Customers



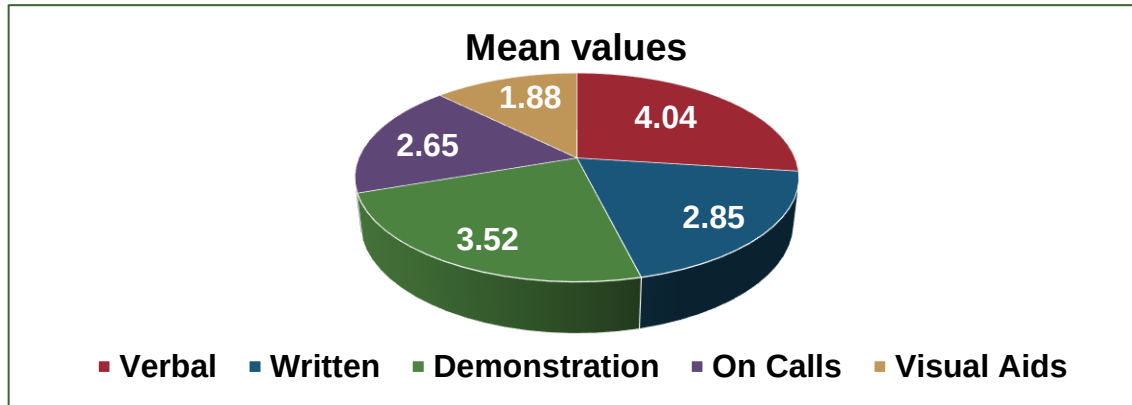
- The top 3 devices are Insulin Pen (Mean = 4.45), Oximeter (Mean = 4.35), and Glucometer (Mean = 4.31).
- Gloves (Mean = 1.34) and Weighing scales (Mean = 1.39) have received less need for counselling.

6. Time taken for Counselling



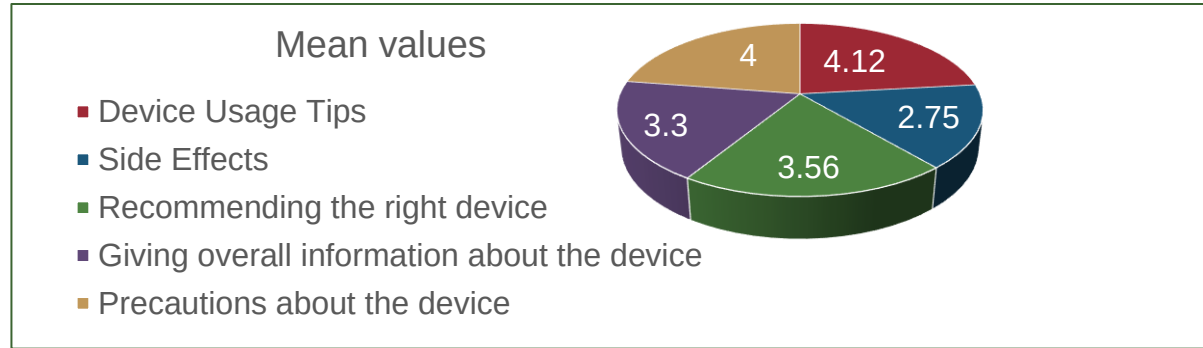
- On an Average, Pharmacists take 1-3 Minutes (54.58%) to counsel their Patients.
- The OTC Medical devices are easier to use and do not take much time to get use to by patients.

7. Methods and Details shared during Counselling



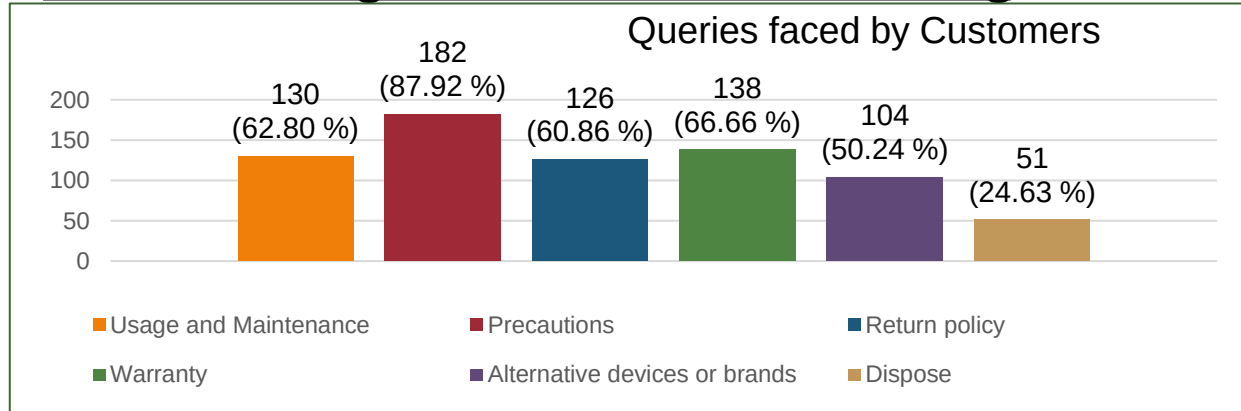
- The major response was given to Verbal (Mean = 4.04) and Demonstration (Mean = 3.52).
- The last response was given to Visual Aids (Mean = 1.88)

8. Device details shared by Pharmacists



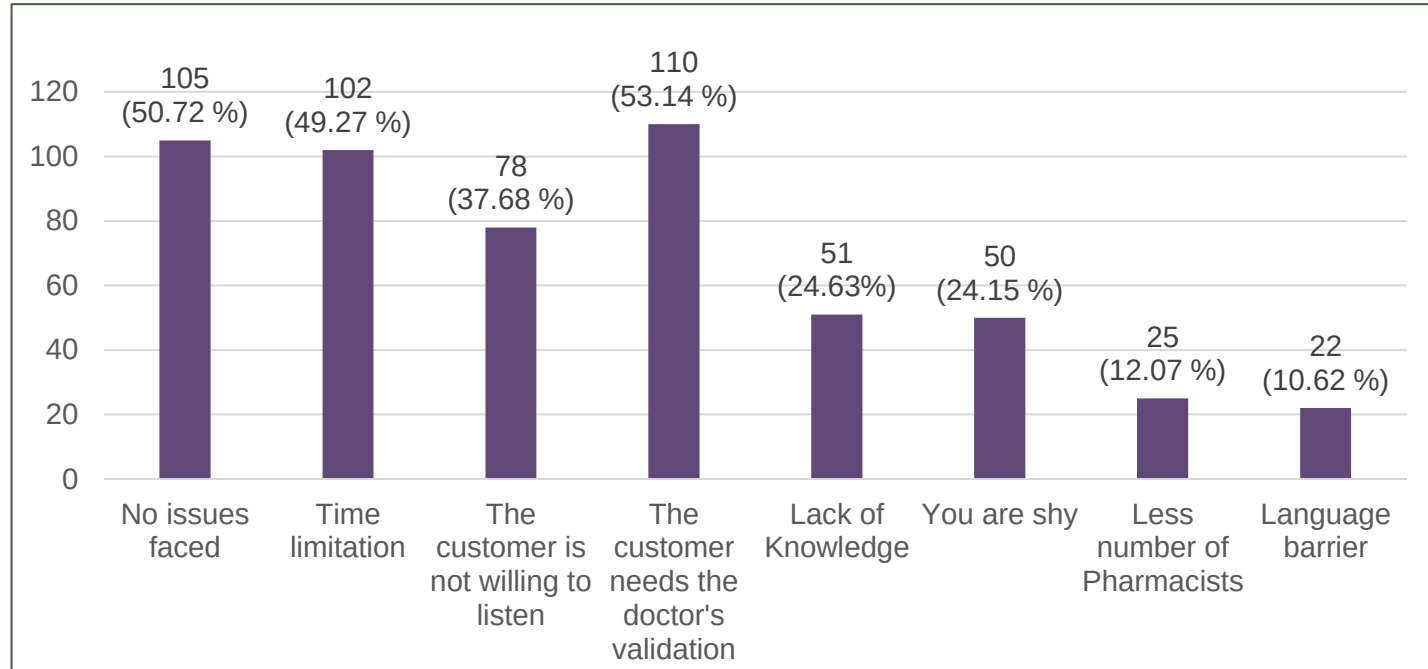
- Details about the Device Usage tips (Mean = 4.12) and Precautions about the device (Mean = 4.00) were highly discussed by the Pharmacists.
- The last response was given to Side effects (Mean = 2.75)

9. Queries during Medical Device Counselling



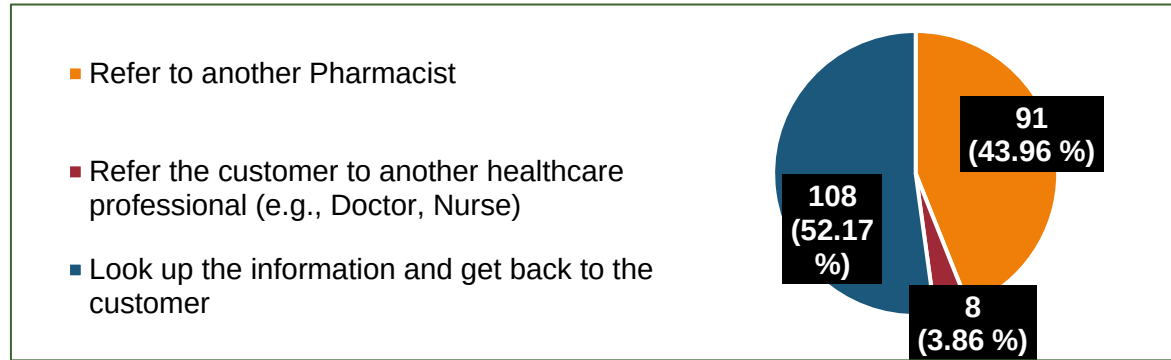
- Most customers have queries regarding Precautions (87.92 %) followed by knowing the Warranty period (66.66 %) and Usage and Maintenance (62.80 %) respectively.
- Least response was given to Dispose (24.63%)

10. Barriers to Medical Device Counselling



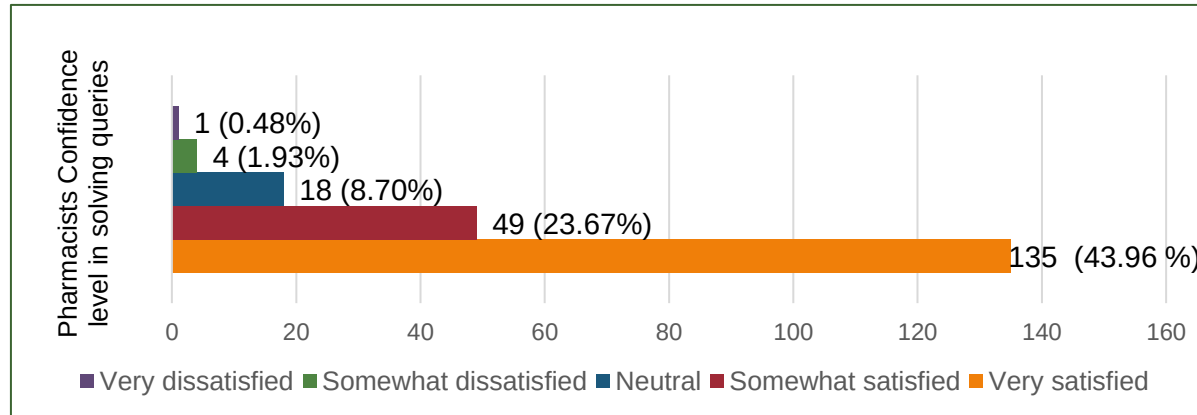
- It can be reported that Customer needs Doctor validation before buying a Medical device from Pharmacists 110 (53.14 %). Many pharmacists showed that they do not face any barriers and can counsel the patients with ease 105 (50.72 %). Time limitation was also observed as a big reason as a barrier to counselling 102 (49.27 %)

11. Ways of tackling unknown Customer Queries



- 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 %).

12. Level of Confidence during Counselling



- 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.

5. Discussion



- Community pharmacists have a significant impact as providers of pharmaceutical and health care.
- Less female respondents indicating them in academics or in managing organizations.
- Gender inclusivity by having respondents as Others
- Less usage of Websites to gather information on Medical devices.
- Customers buy medical devices based on their needs. Devices such as Oximeters, Glucometers, had responses of Good and Very good which indicates such devices are not bought that frequently but the demand for them is increasing.
- Devices which are bought more (Gloves) need not necessarily require a prominent level of counselling.
- Precise Counselling is done (1-3 minutes) along with Verbal demonstration which helps customers to easily understand and keeps them engaged.
- The biggest challenge is Patients need a doctor's validation before trying the medical device thus there can be trust issues from buyer's end.
- Pharmacists believe in looking up the answers there and then counselling the patients. This shows that they have the attitude to learn and grow.
- The benefit of doing the survey online helped in reaching the survey across many states of the country. This survey might have Pharmacists introspect the way of their working.
- Limitations faced- Small participation, Possibility of bias in filling the form, Offline surveys can be more accurate.

6. Conclusions



- 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.
- The current study of self-reporting counselling practices connected to medical devices can be improved.
- Proper patient education on proper usage may not only improve control of the disease's symptoms but may also allow dose reduction over time
- In the future, this research should be taken up at a national level by Government to understand the perception of the Pharmacists, their needs and wants, and Customer queries and how to improve it.



Thank

You!!