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A STUDY ON PURCHASING BEHAVIOUR OF CLASS III MEDICAL INSTRUMENTS AMONG SURGEONS IN SOUTHERN REGION OF TAMIL NADU

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ABSTRACT

In a number of the studies in common theme in purchasing behaviour of the doctor's intention that focus on the need of the product usage in the ICU, Operating room. In this paper effort has been made to identify much surgical equipment for only the doctor's purpose in purchasing medical devices and to analyses the same. A thorough set of hypotheses was proposed, and a technique for testing them was described, based on the existing literature review and framework model. The sample is based on the major cities of Southern Districts of Tamil Nadu respondents. Probability sampling has been used. The study has done about the class III surgical equipment such as , intravenous medications usage of infusion pumps, implantable pacemakers and breast implants, Anaesthesiology, Urology and Plastic Surgery and so on. The results are based on valid 387 responses out of 450, SPSS version 2.1 software. The Price, potential value, and doctor's intention to purchase the class III medical devices had that there is significant difference between the doctor's profile, according to the study's findings. The final result demonstrates that Brand Image has the highest value, indicating that when purchasing the Class III, doctor's choose brand image and lifelong usage over safety to the patients has been used to analyze the results. A larger sample size can be used to obtain more accurate results. This investigation is limited to only the southern Region of Tamil Nadu but future investigations could include other states. It is advantageous to the sales division of the business as well as different distributors that are associated with it. The policymakers and strategy makers of the manufacturing firm will benefit greatly from this study.

Keywords: *Purchase Behaviour, Medical Equipment, Surgical Devices, Doctors' Intention.*

Introduction

The Indian healthcare sector is made up of hospitals, medical equipment, outsourcing, telemedicine, medical tourism, health insurance, and other associated businesses. Healthcare in our country today has exceeded all other industries in terms of employment and money. The requirement for medical equipment is anticipated to increase significantly in order to fulfil the needs of the developing market. The most recent medical technology may considerably improve a doctor running his own practice's productivity, efficiency, and workflow. However, before making a purchase, a doctors have to keep the following in mind.

Products that "typically maintain or support human life, are implanted or provide a possible unjustifiable risk of disease or harm" are classified as Class III devices by the FDA. Medical devices classified as class III include those for where safety and effectiveness cannot be shown by general as well as special controls alone. One of three categories best describes these gadgets:

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- To used to maintain or support human life
- In order to Significantly crucial to preventing harm to human health
- To imply a possible, irrational risk of disease or harm

Medical devices are categorised as class III and are regulated by strict restrictions, the majority of which call for a Premarket Approval (PMA) filing or De Novo. Medical device manufacturers must go through a rigorous PMA procedure that often entails clinical studies and data gathering in order to designate a product as a class III medical device. Devices having a significant equivalence are the only Class III products that are exempt from the PMA procedure. Examining the FDA (PMA) and 510(k) Premarket Notification databases will show if a Class III device may be sold with a 510(k). De Novo is used when there is no legally marketed predicate device for a low to medium risk innovative device. Regardless of critical levels, these devices are automatically classified as class III. The FDA provides a different route to categorise a medical device down to a class I or class II through the De Novo. The device can be used as the basis for additional submissions after it has been declassified and authorised under the De Novo process. Integrated Mutation Profiling of Actionable Cancer Targets in De Novo Devices and the DigniCap Scalp Cooling System. Class III medical equipment comprise, as examples, the following:

- implanted cochlear
- pulse-generating pacemaker that is implantable
- kidney stents
- Automated external defibrillators that can be worn
- ventilators with a high frequency

Regardless of how the medical devices are classified, clinical research must be carried out in one of two methods if clinical data is necessary for clearance or approval:

- It must adhere to the FDA's Investigational Device Exemption (IDE) process if it poses a Significant Risk (SR).
- It will be presented to an Investigational Review Board for review if it fails to present a serious danger.
- The producer will be subject to the strictest level of FDA inspection and related fees in order for a medical device to be classified as a class III device. Only 10 percent of devices are classified as class III, with the remainder being class I or class II. The study has conducted about the doctor’s opinion of class III medical devices. Some the medical devices can see in briefly as below sections.

Pacemaker

A pacemaker is a little device used to treat certain arrhythmias. The heart may beat too quickly, too slowly, or irregularly when experiencing an arrhythmia. With the aid of pacemakers, their heart can beat normally and rhythmically. Pacemakers can also assist their heart's chambers beat in unison so that their heart can pump blood to their body more effectively. If the users have heart failure, they could require this pacemaker. Many pacemaker users are able to resume their normal routines in a few days. They might need to stay away from some electrical or magnetically intense objects.

Cochlear Implantation

An electrical device that helps hearing is a cochlear implant. It may be a possibility for those who are unable to hear effectively with hearing aids due to severe hearing loss brought on by inner-ear damage. A cochlear implant circumvent damaged areas of the ear to send sound impulses to the hearing (auditory) nerve, as contrast to hearing aids which enhance sound.

Ureteral Stents

Thin, flexible tubes called ureteral stents keep ureters open. The urinary system includes the ureters. These thick, lengthy tubes often transport urine from the kidneys to the bladder. To prevent or cure ureteral blockages, medical professionals implant ureteral stents.

The length and diameter of silicone or polyurethane (plastic) ureteral stents range from 10 to 15 inches. They keep the ureter open by lining the full length of it. A coil on the stent's upper portion is placed within the kidney. The bottom end's loop is positioned inside the bladder.

Automated External Defibrillators

AEDs are portable, life-saving medical devices used to treat persons suffering from sudden cardiac arrest, a condition in which the heart stops beating abruptly and unexpectedly. When used during the first few minutes of a collapse caused by sudden cardiac arrest, cardiopulmonary resuscitation (CPR) classes and early defibrillation are successful in saving lives.

High Frequency Ventilation (HFQ)

High-frequency ventilation (HFV) is a kind of mechanical ventilation that blends tidal volumes that are less than the amount of anatomic dead space with very increased respiration rates (>60 breaths per minute). Rarely used and not a first-line mechanical breathing method, HFV should only be managed by qualified practitioners.

Fetal Blood Sampling Monitors

Fetal blood collection is an extremely difficult process. Only a physician with specialised expertise should perform it. When other tests or treatments are not viable or effective, it is used. It is possible for pregnancies that are at least 18 weeks along. At specific points in the course of pregnancy, foetal blood samples are taken in order to diagnose, treat, and assess any issues with the foetus. You might get a sample of foetal blood to:

- Identify chromosomal or genetic abnormalities.
- Examine the kid for severe anaemia and treat it
- Examine and treat further blood issues, such as Rh disease.
- Check the baby's oxygen levels.
- Check the infant for infections.
- Give the infant some medications.

Post Compliances of Class III Medical Devices

Once a product is offered on the market, medical device makers and distributors must also adhere to certain regulations. These prerequisites consist of:

- Medical Device Reporting regulation's requirements for makers, importers, and establishments using devices (such hospitals) to report problems and adverse occurrences (The Indian Central Drugs Standards Control Organization (CDSCO)) in case in USA for ((21 CFR Part 803).
- Tracking programmes to assist with any required product recalls in accordance with 21 CFR Part 821.
- Studies conducted after a PMA, Humanitarian Device Exemption (HDE), or Product Development Protocol has been approved are necessary (PDP). Post-approval studies are required and are a requirement for approval.

Objectives of the Study

- To analyse the doctors' purchase intention of the class III medical devices for surgery.
- To examine the significance of doctor's opinion.
- To propose different strategies and managerial implications for the medical devices' companies based on the findings.

Methodology

The study is a blend of both descriptive and analytical in nature. It is based on both primary and secondary data. The primary data were collected from the Surgeon/Doctors of the nine southern districts of Tamil Nadu. The details were collected from private and public medical health centers. The secondary data were collected from the books, journals, magazines, reports and records, the published and unpublished M.Phil., dissertations and Ph.D., theses and so on.

Sample Size

Initially, based on Rao Soft online sample size calculator was used, which showed 387 as the sample size at 5 per cent significant level.

Sample Design

There are 38 districts in Tamil Nadu. The researcher has chosen the southern districts of Tamil Nadu which consists of nine districts. It was seen that there were 755 Physicians from the selected nine southern districts. Out of the population of 755 Physicians from the nine districts, 387 samples have been selected using the proportionate random sampling method. The following formula is used to determine the sample size in each district in proportion to the total Physicians.

$S = (n / N) * s$

Where,

S = Sample size, N = population of within district,

N = Total population size, s = Identified sample size,

Table - 1 shows the details of the population and sample size drawn from each district.

Table 1: Details of Population and Sample Size Drawn

Sl. No	Name of the District	Total Population Size Considered for the Study	Calculation of Sample Size for each Districts	Sample Size
1.	Thirunelveli	67	=387*(67/755)	34.34305
2.	Madurai	98	=387*(98/755)	50.23311
3.	Dindugal	120	=387*(120/755)	61.50993
4.	Virudhunagar	113	=387*(113/755)	57.92185
5.	Thoothukodi	96	=387*(96/755)	49.20795
6.	Ramanathapuram	70	=387*(70/755)	35.88079
7.	Sivagangai	50	=387*(50/755)	25.62914
8.	Theni	78	=387*(78/755)	39.98146
9.	Kanniyakumari	63	=387*(63/755)	32.29272
	Total	**755**		**387**

Source: Secondary data collected from the Public and private hospital (2022-2023). The sample size of 387 was collected using the simple random sampling method.

Pilot Study and Pre-test

The researcher carried out a pilot study to design the questionnaire. The researcher used the Cronbach Alpha test to conduct the pre-test following the pilot study in order to determine the reliability of the interview schedule. Table - 2 displays the dependability ratings of the replies to the interview schedule that were gathered.

Table 2: Reliability of the Interview Schedule

Sl. No.	Variables	Number of Respondents	Number of Items	Cronbach's Alpha Value
1.	Effectiveness of the Product	70	8	0.718
2.	Perceived Brand Image and Price	70	7	0.722
3.	Easy to access and Convenient	70	7	0.873
4.	Instruction and easy to learn	70	7	0.994
5.	Support and Trust	70	8	0.853
6.	Purchasing Intention	70	8	0.912
7.	Purchasing Experience	70	10	0.705
8.	Availability of Loan for purchase the equipment	70	12	0.701
9.	Perceived Behavioural Control, value and Quality	70	9	0.816
10.	Country of Origin	70	7	0.691
11.	Accommodate the machine in Hospital and post market compliances	70	6	0.814
12.	To Analyse the Risk level of the Patients(Including the Death rate)	70	9	0.734
13.	To analyse the success level after the Operation	70	11	0.792

Source: Primary data

The value of Cronbach's Alpha is shown in Table 2. Accordingly, the Cronbach's Alpha value should be superior to the standard of 0.7. Thus, it can be said that the interview schedule is trustworthy and appropriate for carrying out the research.

Normality of the Interview Schedule

Prior to feeding or importing the data in with any sort of statistical tool application in the study, normality is the key need that helps to check. The primary reason for confirming the data's data is normally distributed is to identify whether statistical methods are adequate and to eliminate outliers from the data. Kurtosis and skewness have been used to achieve the desired level of data normalcy. The distribution height is explained by kurtosis, while the distribution balance is explained by skewness. The skewness and kurtosis benchmark range is between -1.5 and +1.5. Table 3 displays the findings of the interview schedule's normalcy.

Table 3: Normality of the Interview Schedule

Sl. No.	Variables	Number of Respondents	Skewness		Kurtosis	
			Statistics	Std. Error	Statistics	Std. Error
1.	Effectiveness of the Product	387	0.358	.117	0.353	.215
2.	Perceived Brand Image and Price	387	0.101	.117	-0.091	.215
3.	Easy to access and Convenient	387	0.233	.117	-0.613	.215
4.	Instruction and easy to learn	387	0.527	.117	-0.641	.215
5.	Support and Trust	387	0.741	.117	1.446	.215
6.	Purchasing Intention	387	0.861	.117	-0.416	.215
7.	Purchasing Experience	387	0.360	.117	0.353	215
8.	Availability of Insurance for purchase the equipment	387	0.570	.117	0.719	215
9.	Perceived Behavioural Control, value and Quality	387	1.161	.117	0.376	215
10.	Country of Origin	387	1.254	.117	0.369	215
11.	Accommodate the machine in Hospital and post market compliances	387	1.058	.117	0.271	215
12.	To Analyse the Risk level of the Patients(Including the Death rate)	387	1.036	.117	0.261	215
13.	To analyse the success level after the Operation	387	0.612	.117	0.914	215

Source: Primary Data

The normalcy of interview schedule variables, as determined by skewness and kurtosis, is displayed in Table 3. All skewness scores that lie between the ranges of -1.5 and 1.5, or between 0.101 and 0.861, are considered. As a result, it fits the bill. The values for the kurtosis lie within the range of -0.091 to 1.446, which is a suitable height. All of the variables utilised in the interview schedule, according to this statement, are normally distributed. As a result, both parametric and non-parametric statistical test techniques can be used for the investigation.

Socio-Economic Status of the Respondents

The profiles of 387 respondents who have purchased class III medical devices were taken for this study. The details of the respondents have been shown in Table - 4.

Table 4: Demographic Profile of the Respondents

Personal Background	Particulars	Number of Respondents	Percentage
Gender	Male	234	60
	Female	153	40
	Total	387	100
Age	30-64 years old	219	56
	65 years old	168	44
	Total	390	100

Medical Devices Usage purpose	Stroke	149	38.5
	Heart attack	70	18
	Oxygen levels	53	13.6
	Pregnancy	84	21.5
	Transplant the organs	21	5.8
	unreasonable risk of illness	8	2.1
	Disability	2	0.5
	Total	390	100
Medical device Brand	Abbott	23	5.94
	Biotronik	9	2.32
	Medtronic	100	25.83
	NASAN	89	22.9
	Cochlear™ Nucleus® Implants	17	4.39
	Kanso Cochlear Implant	15	3.87
	Ureteral Double J Stents.	32	8.26
	Stent Introducer Set.	23	5.94
	One touch Verio Flex Blood	12	3.10
	Meditive	4	1.03
	Newnik	1	0.25
	BPL Medical	12	3.10
	Philips	50	12.91
	Total	390	100

Source: Primary Data

Table - 4 shows that about the majority of the doctors are male (60%) and 40% are the female. The age of the respondents are the majority level (in 56.2%) 30- 64 years old and least level is (6.7%).

The purpose of the medical devices for stroke (38.5%) is the majority level followed by the heart rate (18%) majority level. The medical devices brand are topmost place is kept by Medtronic Product for Glucometer (25%), NASAN (22%).

Purchase Behaviour of Class III Equipment and the Demographic Profile of the Doctors – Multiple Regression

Class III devices often maintain or support life, are implanted, or carry a disproportionate risk of disease or harm. Implantable pacemakers and breast implants are two examples of Class III medical equipment. This group of gadgets comprises 10% of all medical devices. The researcher has identified the purchase behaviour of class III equipment and the demographic profile of the doctors as dependent variables which are compared with the gender, age, Medical Devices Usage purpose, medical devices brand are considered as an independent variable for using multiple regression. In order to find out the any relationship between the respondents profile and their purchase behaviour of medical devices, the researcher has administered the multiple regression.

Multiple regression is an extension of the simple linear regression. It is used to study about the effects of relationship between one dependent variable and more than one independent variable. The predicted variable is considered as dependent variable. The variables used to predict the value of dependent variable is called the independent variables or predictors. Here, the predicted (dependent) variable is the purchase behaviour of medical devices and the predictors are gender, age, medical devices usage purpose, medical devices brand. For the multiple regression, the null hypothesis is that respondent's profile does not have the significant effect on their purchase behaviour of medical devices. For testing the model, ANOVA test has been used. The null hypothesis is that the model is not fit.

Table 5: Purchase Behaviour of Medical Devices – Model Summary

Model Summary[b]					
Model	**R**	**R Square**	**Adjusted R Square**	**Std. Error of the Estimate**	**Durbin-Watson**
1	.219[a]	.107	.068	2.17201	2.305
a. Predictors: (Constant), Age, Gender, Medical Devices Usage purpose , medical devices brand					
b. Dependent Variable: Purchase behaviour of medical devices					

Source: Primary Data

Table - 5 explains the model summary. R value is 0.219 is a measure of linear correlation of all the independent variable with the dependent variable. R square represents how the data are closeness to the fitted regression line. It is also known as coefficient of determination. The value of R square is 0.107 and the adjusted R square value is 0.68 which shows the proportion profile of the doctors which is closure with their purchase intention of class III devices.

Table 6: Purchase Behaviour of Medical Devices – ANOVA

ANOVA[a]						
Model		**Sum of Squares**	**DF**	**Mean Square**	**F**	**Sig.**
1	Regression	36.076	5	10.015	3.153	.002[b]
	Residual	2148.679	386	6.003		
	Total	2374.755	385			
a. Dependent Variable: General_Barriers						
b. Predictors: (Constant), Age, Gender, Medical Devices Usage purpose , medical devices brand						

Source: Primary Data

The ANOVA Table - 6 indicates the significant value is less than 0.05 which means the regression model is statistically fit.

The Table - 7 presents the multiple regression and the significance level of profile of the doctors and Purchase Behaviour of Medical Devices.

Table 7: Purchase Behaviour of Medical Devices – Coefficients

Model		**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**Sig.**
		B	**Std. Error**	**Beta**		
1	(Constant)	11.740	.796		14.750	.000
	Gender	1.963	.423	.301	.244	.002
	Age	1.757	.403	.304	1.002	.004
	Medical Devices Usage purpose	0.184	.682	.160	1.186	.000
	medical devices brand	1.028	.121	.110	.228	.000

Source: Primary Data

From the above result the regression equation is framed as follows:

Y = a + bx1 + bx2 + bx3 + bx4 + bx5

Where Y= Constant,

A = Dependent variable

B = Independent variables

The null hypothesis is rejected for the type of business as the p-value is less than 0.05 significant value. This means the respondents the respondents profile has significant their purchase behaviour of medical devices.

Findings and Suggestions

One of the numerous lessons learned from this epidemic is that people cannot completely rely on others for maintaining their good health. Individually, as a family, and as a group, people are accountable for their eating habits, personal hygiene routines, and methods of avoiding discomfort or disease.

It is crucial to rely on key medical equipment to monitor the fundamental health indicators that can warn the doctors on any irregularity in the physical state in addition to frequently assessing themselves with medical professionals. For instance, if they have the correct tools, the consumers may quickly prevent and identify significant non-communicable chronic illnesses including cardiac arrhythmias, and diabetes mellitus. Additionally, they must have the bare minimum of medical supplies to provide first aid or determine whether a trip to the hospital is necessary for consultation. Class III medical equipment are risk related to the users. At the last level, doctors were taken the measures to the patients.

By applied the multiple regression, the researcher found that the demographical profile of the doctors that significantly relation to purchase intention of the Doctors'.

Conclusion

Performing surgical procedures is one of a medical facility's primary duties. The number of successful procedures carried out by a hospital's medical staff is frequently used to assess its reputation. To guarantee that all surgical procedures are carried out safely, hospitals must have the necessary operating room equipment available. Medical equipment can be applied alone or in conjunction with any accessory, consumable, or other piece of medical equipment for the particular objectives of diagnosing and treating diseases, as well as for rehabilitation following illness or accident. Implantable, single-use, and disposable medical devices are not considered to be medical equipment.

According to the survey, the doctors chosen branded products with a strong social reputation when purchasing medical equipment. Price is not a significant factor for the responders in this study, though it may have been. The responses are from the same people who were utilising pricey equipment for different purpose. Additionally, our responders included hospitals and private doctors who could readily afford the equipment. The patients can claim by their insurance also. Doctors are highly recommending the above medical devices and advise to purchase these devices. There are many brands being recommended by the doctors through word of mouth namely, Philips, Meditive, Newnik, Abbott, Biotronik and so on and ease to use.

The use of medical equipment class III has given patients a number of advantages, including enhanced quality of life and financial savings. However, it also comes with certain hazards and difficulties. The Food and Drug Administration (FDA) is actively ensuring the safety and secure use of medical devices through the Medical Device Use Initiative after taken the surgery.

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