A pilot study on perception of home glucose testing of diabetic patients in India

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree

of Master of Business Administration (MBA)

in

Hospital and Health Management

by

Prarthita Mukherjee

Under the Supervision and Guidance of

Dr. Mamta Chauhan
Professor, IIHMR University

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled "A pilot study on perception of home glucose testing of diabetic patients in India" 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Prarthita
Mukherjee

Date

CERTIFICATE

This is to certify that Prarthita Mukherjee in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur has successfully completed her/his internship at Orbees Medical during February 20- May 19, 2023.

Place: Hyderabad

Jonathan Pillai
Orbees Medical

CERTIFICATE

This is to certify that dissertation titled "A pilot study on perception of home glucose testing of diabetic patients in India" is a record of the research work undertaken by Prarthita Mukherjee in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Dr. Mamta Chauhan
Professor
IIHMR University

Acknowledgements

It is my immense pleasure to record my deep sense of gratitude and sincere appreciation to every one of those who helped, guided, suggested, cooperated, and inspired me in this journey.

I am immensely delighted to express categorically with a profound sense of gratitude to my respected teacher and esteemed research Supervisor, **Dr. Mamta Chauhan,** Professor, IIHMR University, Jaipur. I am grateful to her for being tolerant of my shortcomings, delays, and professional limitations and for always helping me to clear my doubts and difficulties through her enlightening guidance, inspiration and wisdom. I couldn't complete my research work without her keen involvement in observation, expert knowledge, and deep insight into the subject.

I am also grateful to all the respondents who have been an active participant in the process and have made it possible for me to collect data from them.

I would like to thank my friends who have helped me keep calm and patient and supported me, Deepti, Pradipta, Jayeeta and Manjaree.

I would like to extend my gratitude to my organization Orbees Medical for giving me the space and opportunity to learn and grow in the last few months of internship. Orbees Medical helped me broaden my vision in innumerable ways and I am very grateful to them.

I also take this opportunity to remember and be thankful to my uncle, Dr. Bhaskar Mukherjee who has been a constant guide for me on this journey and has helped me with all means.

I would like to express my gratitude to my mother Smt. Sujata Mukherjee, and Dr. Pradip Kumar Mukherjee for their constant help, sincere encouragement, blessings, love, patience, and sacrifices throughout my research work and for being my pillars of support.

List of Abbreviations

IDF - International Diabetes Federation
AIDS - Acquired Immune Deficiency Syndrome
DALY - Disability Adjusted Life Years
NCDs - Noncommunicable Diseases
SDGs - Sustainable Development Goals
UN - United Nations
WHO – World Health Organization
ATC - Awareness Treatment and Control
SMBG - Self-Monitoring of Blood Glucose
CBG - Capillary Blood Glucose
CCEBDM - Certificate Course in Evidence Based Diabetes Management
NDEP - National Diabetes Educator's Programme
DMDEA - Dr. Mohan's Diabetes Education Academy

CONTENTS

Chapter 1: Introduction

Diabetes is a lifelong condition which consists of a phenomenon of high blood glucose levels. This phenomenon occurs when the body is incapable of producing the necessary amount of insulin or even if it is producing insulin, it is not able to use it efficiently. Insulin is responsible for regulating blood sugar and allowing it to enter cells for energy. When glucose levels remain elevated in the bloodstream, it can lead to various health complications over time. While there is no known cure for diabetes, it can be managed effectively through lifestyle modifications, medication, and regular monitoring of blood glucose levels. Proper management aims to prevent complications and maintain overall health. It's important to note that terms like "a touch of sugar" or "borderline diabetes" can undermine the seriousness of the condition. Every case of diabetes requires attention and proper management to ensure the individual's well-being.[1]

The rapid growth in diabetes cases is linked to population ageing, poor diet, and rising obesity rates. A stroke, heart disease, or other health consequences happen way higher chances to occur in people suffering the syndrome. In the past, many patients diagnosed with Type 2 diabetes regularly self-monitored their glucose levels in their blood at home as part of routine management. For some people, this can provide them comfort regarding their blood glucose levels. Self-monitoring is expensive, and it has been hotly argued whether it should be done on a regular basis.

It is a non-reversible condition and leads to the increase of mortality and morbidity thus creating a huge burden on out-of-pocket expenditure. Reports claim that in 2021 globally there have been over 6.7 million deaths due to diabetes. According to some estimation made by The International Diabetes Federation (IDF)[2] they have claimed that in the year itself around 537 million persons were already living with the disease condition. The same report claims that by 2030, the number in diabetes affected person will severely rise to 643 million if certain preventive measures are not taken. Over 542 million persons are currently facing a risk of getting affected by diabetes due to their mismanaged lifestyle.

Diabetes has been considered as to be a catalyst for various other health conditions hence it has significant amount of effect with its onset. Many people who have obesity occurrence are prone to diabetes. This condition is more fatal than breast cancer and AIDS combined. The most commonly occurring co-morbidities of diabetes are kidney disease, blindness, hypertension, obesity, amputations, dyslipidemia, hypoglycemia, cardiovascular disease, and risk of heart attack or stroke. Therefore, understanding the grave condition of this disease researchers need to adopt much more comprehensive treatment to address diabetes in order to improve the lifestyle of the innumerable number of persons struggling with the condition on a daily basis.

Maiti, Mohanty and Upadhyay (2023)[(3)] stated in their study that during the period of 1990-2016, DALY related to diabetes had risen two-fold. It has been found out that in low- and middle-income countries the occurrence of the health condition of diabetes have been very high almost 75%. Diabetes is connected to practically all chronic illnesses. It makes medical care more challenging and makes chronic illnesses worse. Diabetes increases the chance of amputation of body limbs, loss of eyesight, and premature mortality by deteriorating the eyes, kidneys, nerves, and heart over time.

Diabetes-related medical costs were calculated to be almost up to 966 billion American dollars globally in 2021 and are expected to increase to 1028 billion American dollars by 2030. The reduction of premature mortality due to noncommunicable diseases (NCDs) by one-third is listed under Target 3.4 of the Sustainable Development Goals (SDGs) which the United Nations (UN) has published, which cannot be accomplished without the prevention and treatment of diabetes. The Global Diabetes Compact, an international project led by WHO, was introduced in 2021[(3)] to address sustainable improvements in diabetes prevention care and management.

The key is to detect it as early as possible which will substantially reduce the disease burden of diabetes and make space for a productive life. Since the disease is irreversible, raising Awareness Treatment and Control (ATC) is essential to lowering its impact. The socioeconomic gradient at ATC is significant. The neediest people are the ones who are least likely to obtain medical care, according to Hart's inverse care law. Low socioeconomic level people are typically under aware of, not properly treated, and have a lower control of their condition of diabetes.[(3)]

Types of Diabetes

Type 1

In Type 1 diabetes the most striking feature is the deficiency of insulin production which is also called insulin-dependent, juvenile, or childhood-onset, which must be treated with regular insulin therapy. In 2017, reports found out that globally nine million people got affected by the condition and the majority chunk are from high income nations. Its methods and etiology of prevention are yet to be discovered.[(4)]

Type 2

Type 2 diabetes affects how your body uses sugar (glucose) for energy. If untreated, it can lead to high blood sugar levels because it interferes with the body's ability to use insulin. Over time, type 2 diabetes has the potential to cause significant injury to the body, especially to the nerves and to the blood vessels. Type 2 diabetes is largely avoidable. Genes, being overweight, and insufficient physical activity are all risk factors for type 2 diabetes. Early identification is essential to prevent the worst side effects of Type 2 diabetes. The simplest way to detect diabetes early is to get frequent checkups and blood testing at the doctor's chamber. Earlier it was found to be occurring in only adults and hence was named adult onset but in recent times, it is being seen to occur in children as well. But unfortunately, symptoms of Type 2 diabetes are so mild that it might take a substantial number of years to go on by before even noticing the preliminary symptoms of diabetes. By this time complications are usually aggravated.[(4)]

Symptoms of Diabetes:

A few commonly found symptoms occurring in patients suffering from Type 1 and Type 2 diabetes are listed below:

- Feeling parched
- More than regular urination
- Losing weight in an alarming rate without any inputs
- Ketones are found in urine. They are the byproducts of muscle and fat breakdowns, and this phenomenon occurs when the body does nth av enough insulin to process.
- Constant tiredness and weakness

- Irritation and mood fluctuations
- Blurry visions
- Slow healing sores
- Being prone to easy acquired infections especially in gum, skin, and vaginal areas

Other types of diabetes:

Prediabetes and gestational diabetes are another set of diabetes that may be potentially reversible. Prediabetes is the term for when blood sugar levels are elevated but not yet high enough to be classified as diabetes. Diabetes can develop from prediabetes if it is not treated. On the other hand, gestational diabetes appears during pregnancy but usually goes away after giving delivery. Although gestational diabetes may not meet the requirements for a diabetes diagnosis, the levels of blood glucose in pregnant women are greater than normal. Prenatal screening is frequently utilized to make the diagnosis instead of relying exclusively on reported symptoms. Women with gestational diabetes are more prone to experience complications during pregnancy and delivery. Additionally, both the mothers and their offspring had an increased risk of developing type 2 diabetes in later stages of life.[(5)]

In addition to Type 1, Type 2, and gestational diabetes, there are other not so prevalent types of diabetes:

- Monogenic diabetes: This type of hereditary diabetes is brought on by changes in just one gene. It is often diagnosed in childhood or early adulthood and is quite uncommon.
- Diabetes associated with Cystic Fibrosis: Due to pancreatic damage and decreased insulin synthesis, people with cystic fibrosis, a genetic condition that affects the lungs and other organs, may develop diabetes.

Other instances:

Diabetes may be brought on by specific medical problems or drugs. Diabetes, for instance, can be brought on by various hormonal abnormalities, pancreatic conditions, and drug adverse effects.[(1)]

Management of diabetes

Aside from treating diabetes and its effects, there is an urgent need for ways to stop or at least slow down the increasing epidemic of diabetes. The rapid epidemiological transformation brought on by urbanization and lifestyle changes is considered to be the most significant of the many reasons that are assumed to be contributing to the epidemic's escalation. Planning preventive actions requires identifying those who are at risk. There are various windows of opportunity for diabetes prevention.

The four stages of prevention are as follows:

1. Primordial prevention aims to lower the risk factors for diabetes, like lowering or preventing obesity to lower the likelihood of onsetting of the health condition of diabetes in the future.

2. Primary Prevention: In order to prevent the onset of diabetes, primary prevention focuses on patients who are already prediabetic. All individuals with prediabetes should have routine screenings and be urged to adopt a healthy lifestyle that includes a balanced diet, frequent exercise, and weight management in order to prevent diabetes. Up to one-third of persons with prediabetes can avoid developing diabetes, according to numerous research, some of which were conducted in India. Use of metformin in addition to lifestyle changes may be considered, especially in Indians who move to diabetes quickly from the prediabetes stage and especially in those with mixed IFG and IGT where progression to type 2 diabetes appears likely.

3. Secondary prevention aims to stop complications from developing in people with diabetes who have previously been given a diagnosis. This can be accomplished by carefully managing diabetes with the aid of food, exercise, lifestyle changes, and prescribed antihyperglycemic medications. Beyond glucose control, comprehensive treatment should also be provided, such as attention to lipids, blood pressure, and other factors.

4. Tertiary diabetes prevention aims to stop diabetic problems from progressing to end stage issues by reducing physical incapacity and rehabilitative interventions in people who have already developed diabetic complications.

It's crucial to remember that correct management and treatment are necessary for controlling blood glucose levels and reducing the risk of complications, regardless of the type of diabetes.

The management of diabetes requires consistent monitoring, medication, lifestyle modifications, and attention to healthcare provider recommendations.[6]

Self-monitoring of blood glucose levels by people affected by diabetes is an essential component of intense glycemic therapy and is it is also claimed to improve the control of blood glucose and health outcomes.[7]

This pilot study aims to delve deeper into how Indians perceive the home glucose monitoring procedure using home kits.

Implication of research:

This study assessed the level of knowledge and the degree of awareness about the condition of diabetes in the general population, as well as in people currently affected by diabetes and around their glucose monitoring devices that people use daily. The common perceptions regarding the daily used devices will help community to understand if there are any unmet needs or gaps that need to be addressed for better diabetic care management.

Sl. No.	Author/s	Year	Methodology type	Title
1	Suraj Maiti, Shamrin Akhtar, Ashish Kumar Upadhyay & Sanjay K. Mohanty[3]	2023	Report on Secondary data from NHFS-5 of 2019-21	Socioeconomic inequality in awareness, treatment, and control of diabetes among adults in India: Evidence from National Family Health Survey of India (NFHS), 2019–2021[3]
	Findings: Researchers at the International Institute for Population Sciences of Mumbai conducted a study to understand the prevalence, treatment procedures, awareness levels, and control of diabetes of 2,078,315 individuals aged 15 and above in 36 states. It was found out that more people have diabetes than the 16.1% national average in 15 states. Rajasthan has a 10% prevalence, making it the least afflicted state. Meghalaya has a diabetes awareness rate of 14.4%, while Telangana has a level of 54.4%. Males are more likely to be affected than females, and prevalence rises with age. People suffering from diabetes are usually found to live in cities, have small families (fewer than three members), and be married. In India, 32.9% of households or just under one third of all households have at least one diabetic member. More than 40% of families in economically developed areas like Goa, Andhra Pradesh, Tamil Nadu, and Kerala have a diabetic person.[3]			
2	Grand View Research Report[13]	2023	Market analysis report	Blood Glucose Monitoring Devices Market Size, Share & Trends Analysis Report By Product (Self-Monitoring Devices, Continuous Blood Glucose Monitoring Devices), By End-use (Hospital, Homecare), By Region, And Segment

				Forecasts, 2023 – 2030[13]
	Findings: The blood glucose monitoring devices market was estimated at 12.5 billion American dollars in the year 2022, and from the year 2023 to the year 2030, it is expected to amplify at a CAGR of 8.13%. The prevalence of diabetes has been rising and elderly people who are at most risk to get affected by this disease are also growing which makes them the primary drivers of the market. The market's expansion is also aided by new product introductions and rising awareness of diabetes preventive care. Blood-glucose monitoring (BGM) devices have proven to be advantageous to patients suffering from diabetes in four different ways. By allowing patients and physicians to quickly diagnose acute hypoglycemia or hyperglycemia and by empowering patients with more self-care, these devices enable therapy changes and patient protection. Blood glucose devices are available in a wide range of sizes, prices, testing times, and ease of use. The epoch of the covid-19 pandemic turned out to be very beneficial for blood glucose monitoring devices in terms of increasing popularity amongst all devices available in the diabetic care market. It was found out that there has been a small increase in the level of awareness among diabetes affected consumers as well as virtual clinics and telemedicine became more prevalent. Due to its quick response, glucometers demand also rose to a certain extent as compared to other years of sale.[13] A news report in India Today listed out the most used glucometers in India along with its prices.			

Best glucometers in India	Key features	Glucometer price on Amazon (Approx.)
Dr Morepen BG-03 Gluco One Glucometer	Available with a plastic case	Rs 450
Dr Trust (USA) Fully Automatic Blood Sugar Testing Glucometer	Highlights the irregularities in the blood sample	Rs 900
OneTouch Verio Flex Blood Glucose Monitor	Can be connected to the app	Rs 1,100
Accu-Chek Active Blood Glucose Meter Kit	Displays results in just 5 seconds	Rs 1,500
Beato Smartphone Glucometer	Compact and smart device	Rs 1,000
Contour Plus One Blood Glucose Monitoring System Glucometer with 25 Free Strips	Available with an option to connect to the app and view results on your smartphone	Rs 13,00
AccuSure Simple Glucometer Machine with 25 Test Strips	Can store up to 1000 readings with date and time	Rs 500
Control D Glucometer with 25 Strips	Affordable and efficient	Rs 450
OneTouch Select Plus Simple Glucometer	Highly easy to use	Rs 900

Source: The Times of India[14]

3	Prashant Mathur, Sravya Leburu, and Vaitheeswaran Kulothungan[8]	2022	A cross sectional survey article with 12000 households	Prevalence, Awareness, Treatment and Control of Diabetes in India from the Countrywide National NCD Monitoring Survey[8]
	Findings: In India, it was discovered that 9.4% of adults had diabetes. Of these, 15.7% had their diabetes under control, 36.1% were receiving medication, and 45.8% were aware of their diabetes status. Urban areas had a 14.3% prevalence of diabetes, compared to 6.9% in rural areas. However, the			

	fact that adults in rural areas receive less education and care than their urban counterparts is concerning. Women were found out to have higher chances than males to suffer from diabetes diabetes (10.2% vs. 8.5%), but more women had recently been diagnosed (6.0%). In addition, diabetes affected 44.2% of individuals with high cholesterol and 16.3% of those with hypertension. In India, above 3/4th adults prefer allopathic medical doctors in their health seeking behavior when it comes to diabetes. The percentage of rural residents who used AYUSH systems for consultation rose to 24.6%. According to the survey, over 90% of secondary and over 70% of primary public health facilities hardly provided counselling services but offered diabetic management, laboratory, and screening services. Men, older adults, people from urban areas, and those with some education were more knowledgeable about diabetes and its management. For the purpose of creating focused health interventions, it is crucial to understand where diabetics become lost in the care cascade. By 2025, a significant amount of diabetes will be reduced and controlled thanks to population-based screening programs that are implemented on schedule and strengthened primary healthcare.[8]

4	T.K Mathew, and P Tadi[11]	2021	Article	Blood Glucose Monitoring[11]
	Findings: "Blood glucose monitoring looks for patterns in the variations in glucose which is affected by lifestyle and medication changes. If unusual changes are found it is considered to be fatal and will bring about other major complicated diseases. Capillary blood glucose (CBG) tests are frequently used to describe blood glucose monitoring done at home or in the community. Blood glucose testing done in clinical facilities may also include venous blood (plasma glucose) assays."[11]			

5	Anupama Anitha Pavithran, Lakshmi Ramamoorthy, Suryanarayana	2020	Journal on a study on 284 diabetic patients using convenience	Comparison of Fingertip vs Palm Site Sampling on Pain Perception, and Variation in Capillary Blood Glucose Level among Patients with Diabetes Mellitus[12]

	BS, Rajeswari Murugesan, and Kumari MJ[12]		sampling	
	Findings: "Glycaemic status of the patient is often monitored using capillary blood glucose test which is considered to be mostly very accurate. Traditionally the finger pricing method is used which has been found to be painful and leads to a hesitancy amongst diabetic patients to do repeated tests. The study was conducted to draw a comparison between fingertip and palm site sampling on pain perception. And variation in capillary blood glucose level. The data was collected from both the sites at a 10 minutes interval using a regular glucometer. The level of pain perceptions was measured with a numerical rating pain scale. Data was analyzed using descriptive analysis, Mann-Whitney U test and Kruskal- Wallis test. It was found out that 78.52% of the participants experienced more pain at fingertip than palm site. Therefore, an alternate site sampling with very minimal variation in the blood glucose level can also work to reduce the constant pain in fingertips. This can change the perception of diabetic patients towards regular testing."[12]			

6	M. Deepa, A. Bhansali, R. M. Anjana, R. Pradeepa, S. R. Joshi, P. P. Joshi, V. K. Dhandhania, P. V. Rao, R. Subashini, R. Unnikrishnan, D. K. Shukla, S. V. Madhu, A. K. Das, V. Mohan, and T. Kaur[9]	2014	Article in a Journal 16,607 samples Interviewed with a structured questionnaire	Knowledge and awareness of diabetes in urban and rural India: The Indian Council of Medical Research India Diabetes Study (Phase I): Indian Council of Medical Research India Diabetes[9]

	Findings: This study, the first of its kind from India, examines diabetes awareness and knowledge across a representative sample of four areas, with a population of over 200 million. The important conclusions are as follows: (1) Only half the population i.e., 50% in the North, West, East and South regions of India that were surveyed had only just heard of the term "diabetes." (2) There is a considerable gap in the degree of diabetes knowledge between the various study regions. (3) Rural areas have bene found out to have comparatively lower level of awareness in terms of knowledge of diabetes as to that of metropolitan areas. (4) With the exception of Chandigarh, in all the areas under study it was alarming to see that females had lower levels of knowledge of diabetes as compared to that of men. (5) It should come as no surprise that in all four study regions, the self-reported diabetic group has more knowledge of diabetes than the overall community. (6) However, it is also a topic of concern as the people suffering from diabetes also does not have full awareness regarding the disease. (7) According to a composite knowledge score, Tamil Nadu was found to have the highest number of persons with the awareness while Jharkhand was found out to have the lowest amongst all in terms of awareness levels. Maharashtra had the largest number of people with low awareness amongst people who themselves claimed to be diabetic patients and Tamil Nadu had the lowest.[9]

7	Enza Gucciardi, Mariella Fortugno, Andrea Senchuk, Heather Beanlands, Elizabeth McCay & Elizabeth E Peel[10]	2013	Qualitative study	Self-monitoring of blood glucose in Black Caribbean and South Asian Canadians with non-insulin treated Type 2 diabetes mellitus: a qualitative study of patients' perspectives[10]
	Findings: "There have been concerns regarding the cost of blood monitoring of glucose levels through self-administration as patients have to buy lancets, glucometers, and the strips. In some			

	countries like Canada the reimbursement coverage is almost to null. This study was an attempt to understand their perceptions on this method. Each participant highlighted certain obstacles that would prevent frequent use of SMBG. The five issues listed down were the pain in regular pricking, the cost of the device and strips, lack of self-motivation or discipline, home-testing method as a burden and the unpleasant emotions if and when finding about unexpected glucose readings. First, the SMBG values caused some people mental anguish. Second, most participants were discouraged from performing routine SMBG due to the cost of lancets and strips. Caribbean participants, who tended to undergo SMBG more frequently, more commonly identified pricking pain as a barrier than South Asian participants. One participant claimed that the only time he avoided SMBG was due to pricking. Fourth, two South Asian women complained that SMBG was a "hassle" and a technical annoyance since they did not know how to fix the technology if the machines broke down or the batteries aged prematurely."[10]

8	Julienne K. Kirk, and Jane Stegner[7]	2010	Journal article	Self-Monitoring of Blood Glucose: Practical Aspects[7]
	Findings: "Self-monitoring of blood glucose (SMBG) should be a frequent component of a diabetes patient's management strategy. The dynamic blood glucose profile of an individual can be learned by self-blood glucose monitoring. The right timing of meals, activities, and medications can be aided by this information. Understanding the timing of blood glucose fluctuations also depends on it. Hospitalization for diabetes-related complications is predicted by the absence of routine SMBG. For diabetics using insulin or for individuals who experience blood glucose swings, especially hypoglycemia, self-monitoring of blood glucose is a crucial tool. The process of checking blood glucose is made more attainable by the application of practical elements that facilitate simple control of SMBG. SMBG is necessary for people who use insulin and regulate their dosage to control themselves. Profiling glucose patterns and the confirmation of high or low blood glucose can be a helpful addition to effective treatment for those using oral medications. The capacity to manage SMBG depends on the patient's knowledge of diabetes and/or their general comprehension of the fundamental stages involved in managing SMBG.			

	Successful diabetes outcomes need the use of SMBG data for self-management. As a course of action for SMBG outcomes, goal formulation from a health care and patient team perspective can also be helpful. For instance, drugs that target liver output of glucose may be beneficial if the results of the SMBG test reveal a regular pattern of high fasting glucose levels. Two hours after a meal, postprandial glucose levels give information about how food intake affects blood sugar levels. Dietary changes or medication (such as some oral medications or mealtime insulin) may be helpful treatments. The patient's capacity to understand and remember the frequently technical nature of the SMBG process should be carefully evaluated. A key component of a good SMBG will be paying attention to both literacy and numeracy skills. It is crucial that the patient demonstrate SMBG to the diabetes educator or medical professional."[7]

9	Shashank R Joshi, AK Das, VJ Vijay, V Mohan[15]	2008	Journal	Challenges in Diabetes Care in India: Sheer Numbers, Lack of Awareness and Inadequate Control[15]
	Findings: As a society we need to understand the huge economic and physical burden that diabetes carries with itself. Hence as a society we need to take preventive measures like screening as early as possible, monitoring all the risk factors, tight metabolic control, and assessment of any possible damage to organs. Studies show that preventive care for diabetes only costs a fraction of carrying the actual burden with its onset. But when it comes to people from lower socioeconomic backgrounds, they tend to face catastrophic out of pocket expenditure in order to manage diabetes due to the micro complications as well as macro complications of the condition. In the last two decades there has been active efforts to study the pathophysiology of the disease space and the disease intelligence which has resulted in new oral drugs, new insulin and improved delivery systems to control the diabetes situation.[15]			

Chapter 3: Methodology

Rationale:

India is seeing a steep rise in diabetic patients. This has been a concerning topic. It is a genetically carried condition in most families. Hence diabetes space has been an intriguing area of study for many for years.

Going through reports, it was found out that India has been declared to stand second in having the largest number of diabetic patients. In a 2021 projection the age group of 21 years to 79 years, India which currently houses 75 million diabetic patients will increase to 124.9 million diabetic patients by 2045. According to Indian diabetes foundation, one is every third household in India houses a diabetic patient. Nonetheless it has been noticed that there are very less dedicated studies or research on diabetes at a national level. Considering to be a such a common disease and which affects a diverse range and gender of people around the world, it was decided to work on this space especially keeping home glucose monitoring process in focus.[3]

Research questions:

- How accurate do individuals perceive home glucose testing devices to be in comparison to laboratory-based testing in India?
- What are the barriers to adopting home glucose testing as a regular practice in India?

Objectives:

- To study the common perceptions and attitudes of individuals in India towards home glucose testing.
- To understand how the perception of home glucose testing impact self-care behaviors and diabetes management in India.

Research method:

Quantitative research method has been adopted for this study.

Research design:

As, the objective of the study is to have an understanding of the perceptions of individuals regarding the use of home glucose testing devices, the most suitable method was considered to be analytical cross-sectional study design using a survey method to collect data with the use of a tool that is questionnaire.

Sources of Data:

Primary data collected through survey from 100 randomly selected beneficiaries.

Sampling Method:

Convenient sampling method has been adopted for the study. There was no structured pattern followed in order to find the respondents.

In this method, the respondents are those who were the easiest to reach or contact with so that the information gathering process could be made easier. So, it reduced the chances of random selection from a huge population pool.

Sample size:

The study area is India and the country has been segregated primarily into 4 zones North, East, West and South and other zones that respondents are residing in like north east zone, central zone etc. 100 respondents were selected for the study. The respondents were either diabetic patients themselves suffering from either type 1 type 2 diabetes or the respondent could be a care giver

who actively takes parts in the monitoring of the glucose levels of a diabetic patient using home glucose testing kits.

Process of Data collection:

A web-based questionnaire, consisting of 20 question and prepared through Google Form, was sent to 130 known patients/caregivers from four corner (NEWS) of India through email and social media platforms. Of the total sent, 82 questionnaire was received. A few (less than 3%) responded intimated their unavailability/sharing perception. A follow email was made twice to gather more opinion from the respondent, which returned another 18 responses. So the sample consists of 100 respondents who belong to various region of India. Questionnaires were prepared to keep in mind the objectives proposed for the study.

Process of Data analysis:

The collected data from 100 samples has been analyzed with the tool – Microsoft Excel.

The collected questionnaires were initially categorized and coded under several headings in order to conduct a systematic analysis of the data. Additionally, tables were made according to the need. The data were fed into MS Excel after data coding. The data was analyzed, and comprehensible presentations of the statistical findings were made. Following tabulation, the data tables were explained in order to reach a conclusion and draw inferences. As a final outcome, a research report is prepared.

Limitations of research:

Every research study has its limitations and so the present study is not an exception. The scope of the research was limited because it could not cover the entire country and only a small subset of the population was chosen due to paucity of time. This means that the findings of this research which is being conducted must not be generalized for the entire nation.

Ethical responsibilities:

- Proper consent was taken from each participant.

It was made sure that all the participants who are a part of the research have taken part voluntarily by their own choice and they also were provided with prior information about what the study is about, their roles, and they have to kept in loop with the result in order to avoid alienation of the product of the study.

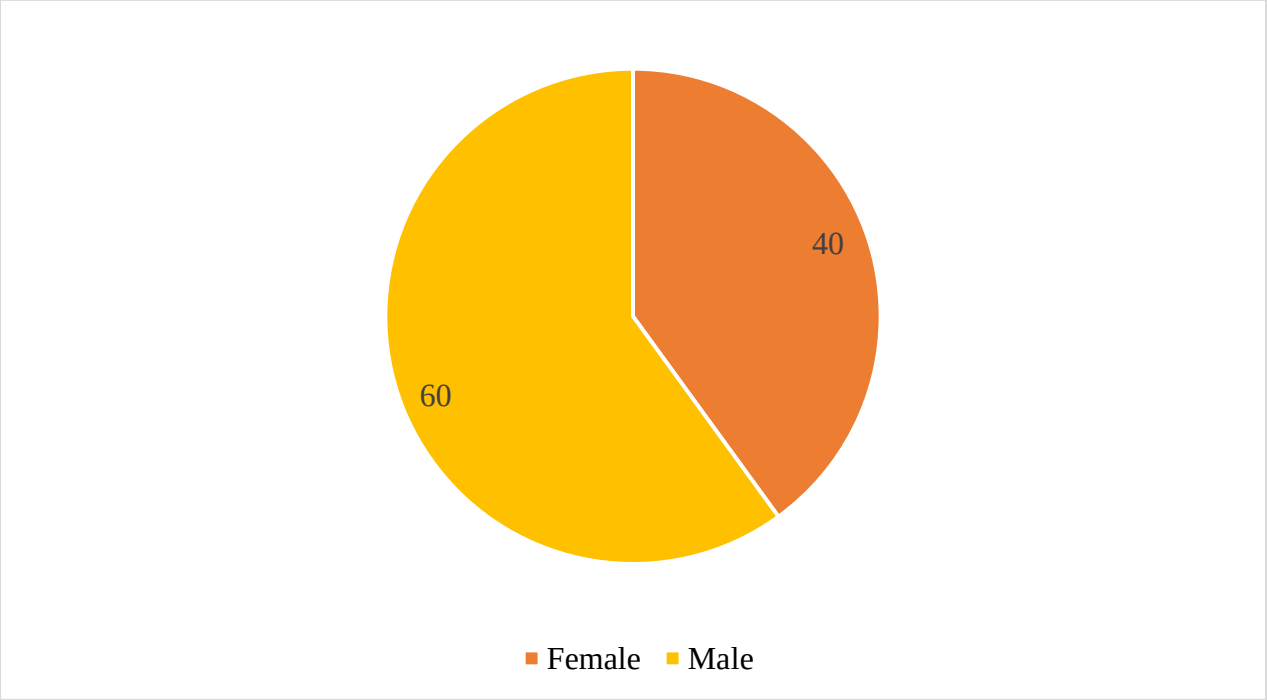
- Anonymity and confidentiality of each participant was respected and protected.

Any personally identifiable information submitted by participants were edited in the name of confidentiality and anonymity.

Chapter 4: Results and Discussions

In this section a methodical approach of analysis to the data based on the received opinions from the respondents has been provided.

A. Distribution of Respondents by Gender

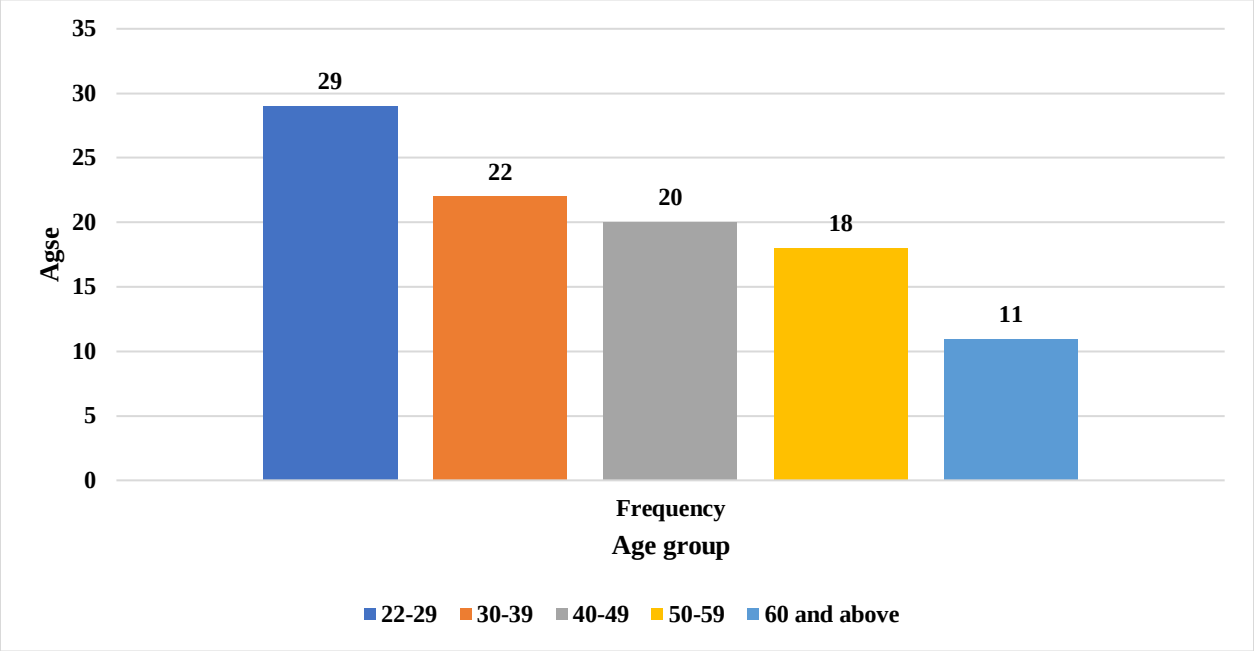


Interpretation:

Figure 'A' shows the distribution of respondents by gender. As shown in the pie graph respondents almost equally from two genders with a slight higher by men. The even distribution among female and male is positive indicator to draw a balanced conclusion.

The respondents of the study belonging to various age groups. The distribution of the respondents based on age was grouped as between 20 - 30 Years, 31- 40 years, 41-50 years 51-60 years and above 60. The same is presented in Figure 'B'.

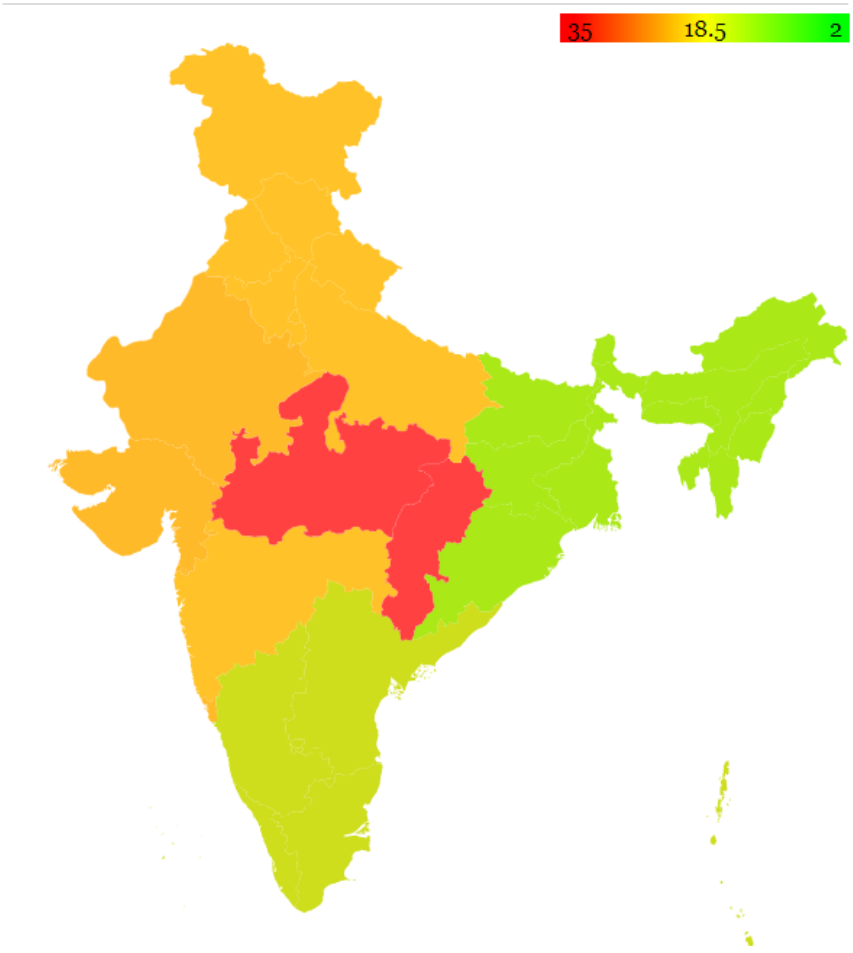
B. Distribution of respondents by Age



Interpretation:

Figure 2 shows the distribution of respondents by their age. As shown in the bar graph, almost half of our respondents are below the age 40 and remain half above 40. Studies have shown that Diabetes affects men and women if different ways and people over the age of 40 are more prone to diabetic. Therefore, women aged above 40 need to adopt preventive measures in order to maintain their glucose levels in ideal check. Even though type 1 diabetes occurs only during childhood or early onset of adulthood, yet it can come to surface in later stages of life. As per medical suggestion, one should track his/her blood sugar level at a regular interval whenever he/she reaches at the age 40.[6]

C. Distribution of Respondents by Regions of India

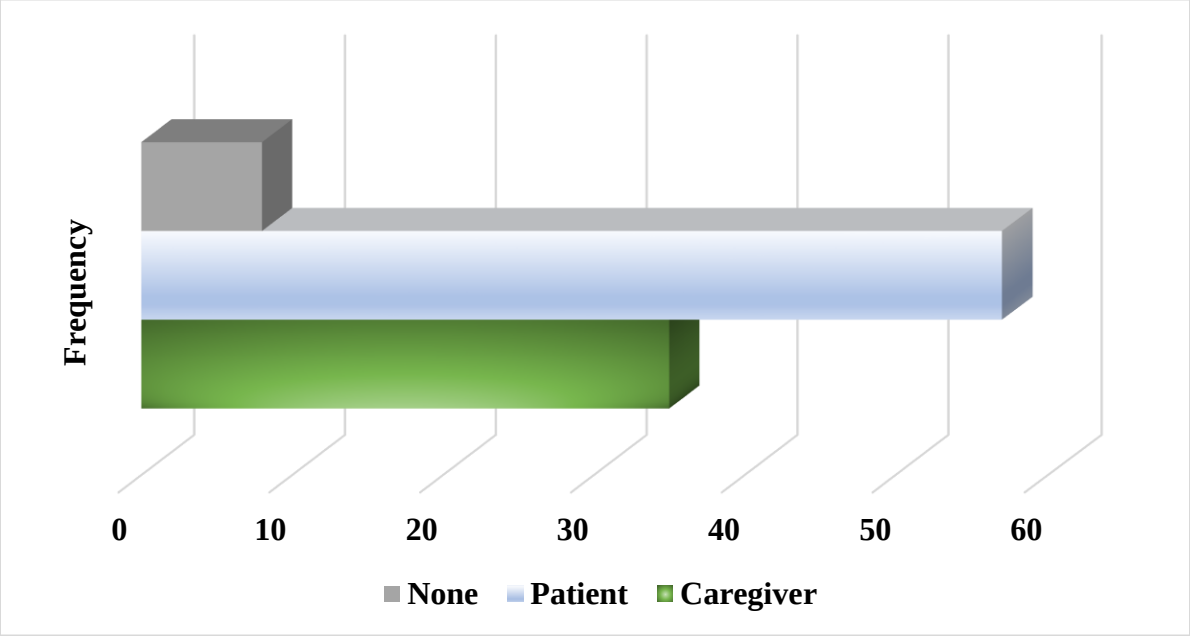


Central	**2**
East	**35**
North	**17**
North-East	**2**
South	**28**
West	**16**

Interpretation:

35% respondents were from the East. The questionnaire being rolled out from the east and snowballing method being used it is justified that the maximum respondents were from the east. Followed by 28% from South, 17% from the North and 16% from the West. The rest reported from central region and northeast.

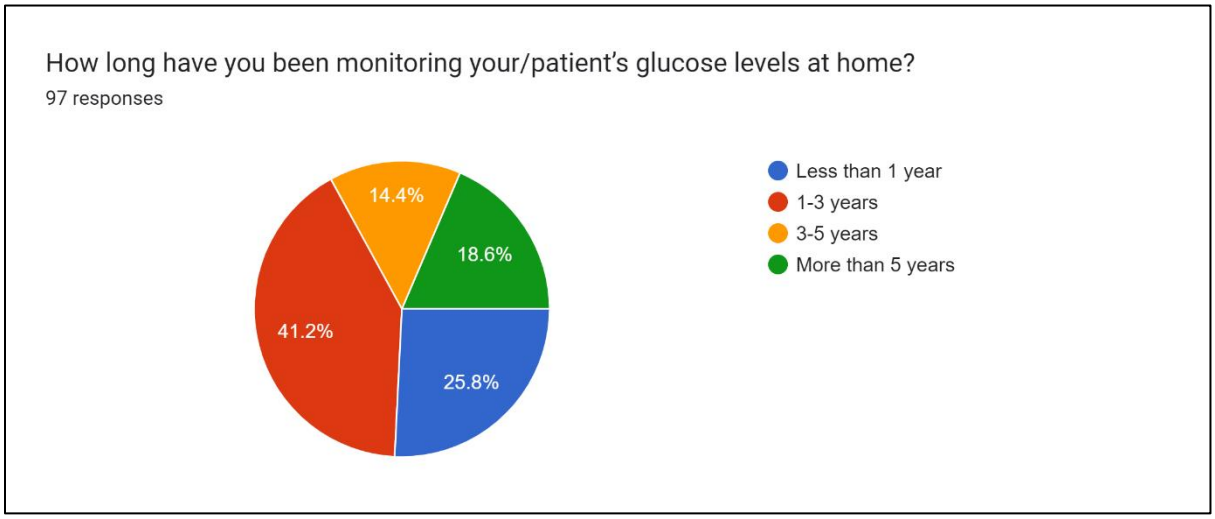
D. Distribution of respondents according to Diabetic Status



Interpretation:

The maximum respondents that is of 57% are patients themselves who themselves answers the questionnaire followed by 32% caregivers who are in charge of taking regular care of a diabetic patient. The other respondents were close family members as they live in close quarters with a diabetic patient but are not patient or caregiver themselves. They are related to the patient through kinship.

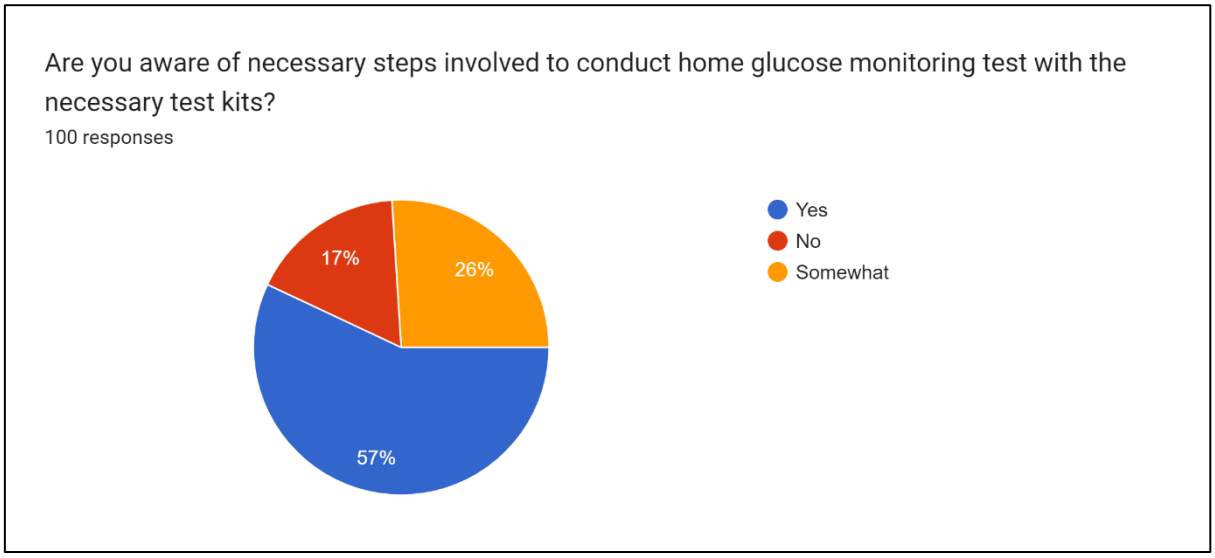
E. Time of Monitoring of Glucose level - Frequency



Interpretation:

41.2% reported to have been in the process for a period of 1-3 years. Around 26% reported to have started just recently and has not yet completed a year yet. So, the respondents are still amateur at getting familiar and skillful at this process of finger pricking for blood glucose testing. The rest of the 32% is distributed across people who are 3-5 years or more than 5 years into the process.

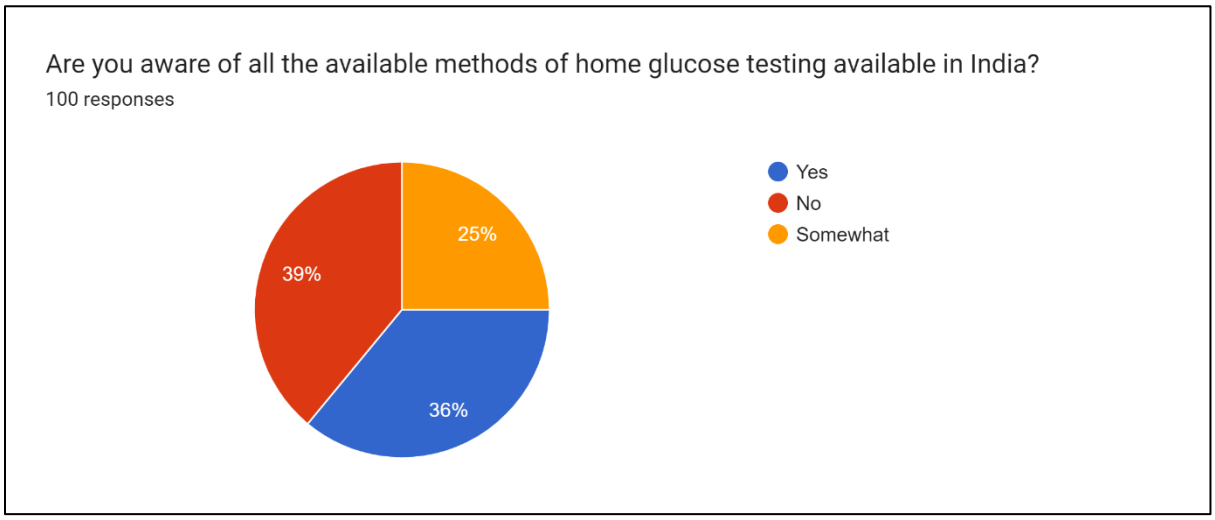
F. Awareness of respondents on Glucose monitoring Test



Interpretation:

Even though 57% respondents did say that they are aware of how to conduct home glucose monitoring test with necessary test kits, 26% reported that they somewhat know of the process. In a small sample size of 100 one-fourth population responding they are not sure is a sign of direction that a lot needs to be worked in terms of spreading awareness amongst people who must conduct regular finger pricking for glucose testing. An individual needs to be aware of every procedure that is being administered on their body.

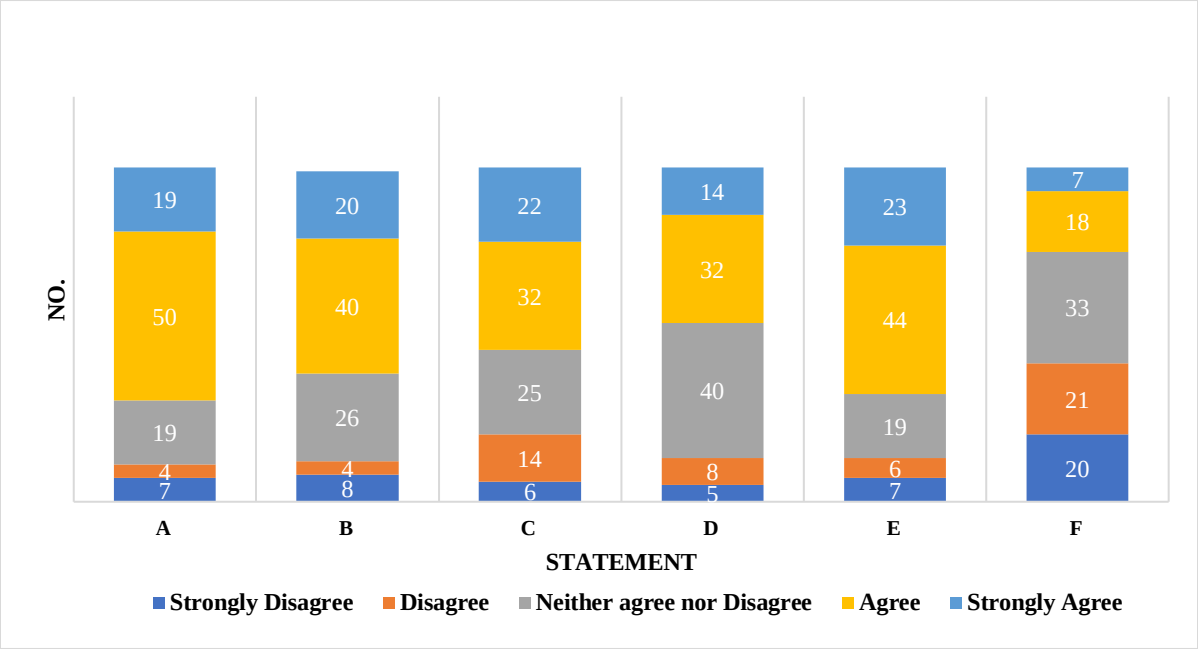
G. Awareness of respondents on all Alternative Home Glucose Testing methods



Interpretation:

The majority respondents didn't know about all the available methods of glucose testing available in India which are available other than lancet, strip and glucometer or were somewhat informed about them i.e., 39% and 25%respectively. Only a 36% were aware of all the methods. The larger population being on the unaware side makes us question the level of awareness of consumers and diabetic patients as the diabetic market also has continuous glucose monitoring systems.

H. Perception on Home Glucose level monitoring



Interpretation:

This graph is to understand the overall perception of respondents on home glucose monitoring process using devices like glucometers.

A) Home glucose monitoring is convenient. 50% agreed to the statement only 11% respondents did not agree to this or strongly disagreed. 19% strongly agreed to glucometers being very convenient.

B) Home glucose monitoring helps in better diabetes management.40% agreed, 20% strongly agreed and 12% disagreed or strongly disagreed.

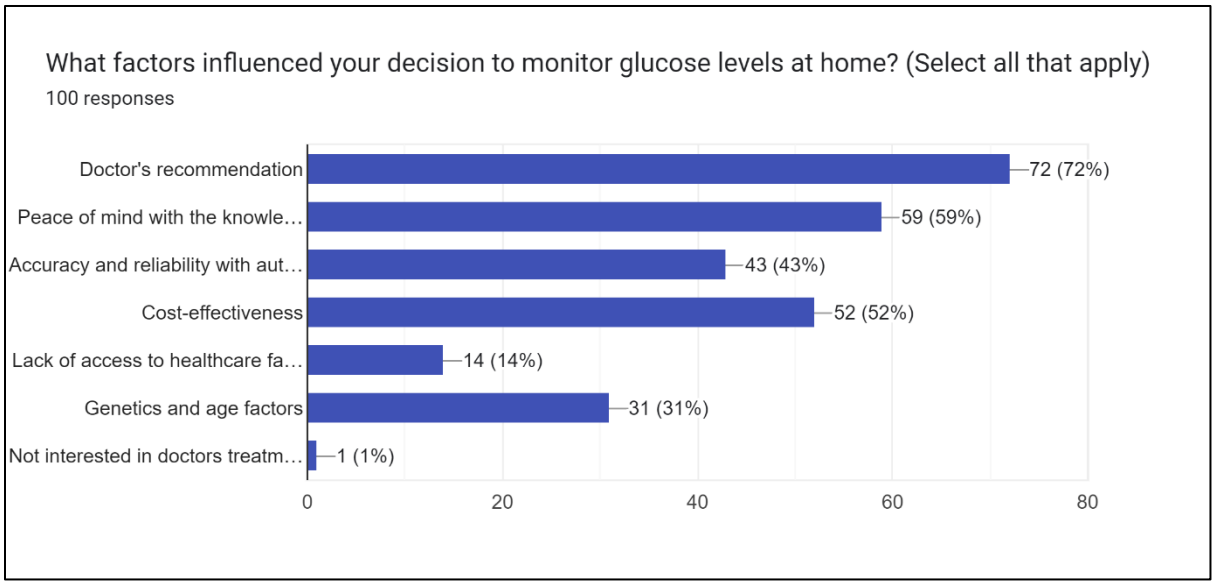
C) Home glucose monitoring makes me/patient skeptical due to the finger prick method. 54% reported that they have been scared of finger pricking. This has a lot of repercussions on the use of glucometers.

D) Home glucose monitoring is accurate and reliable. While the major chunk of 40% were neutral about the accuracy and reliability, 46% expressed their lack of faith in the process.

E) Home glucose monitoring saves time and effort. 67% agreed to this statement.

F) Home glucose monitoring is a burden. This statement received mixed responses. 33% had centralized views on this. 25% agreed to this and 41% disagreed.

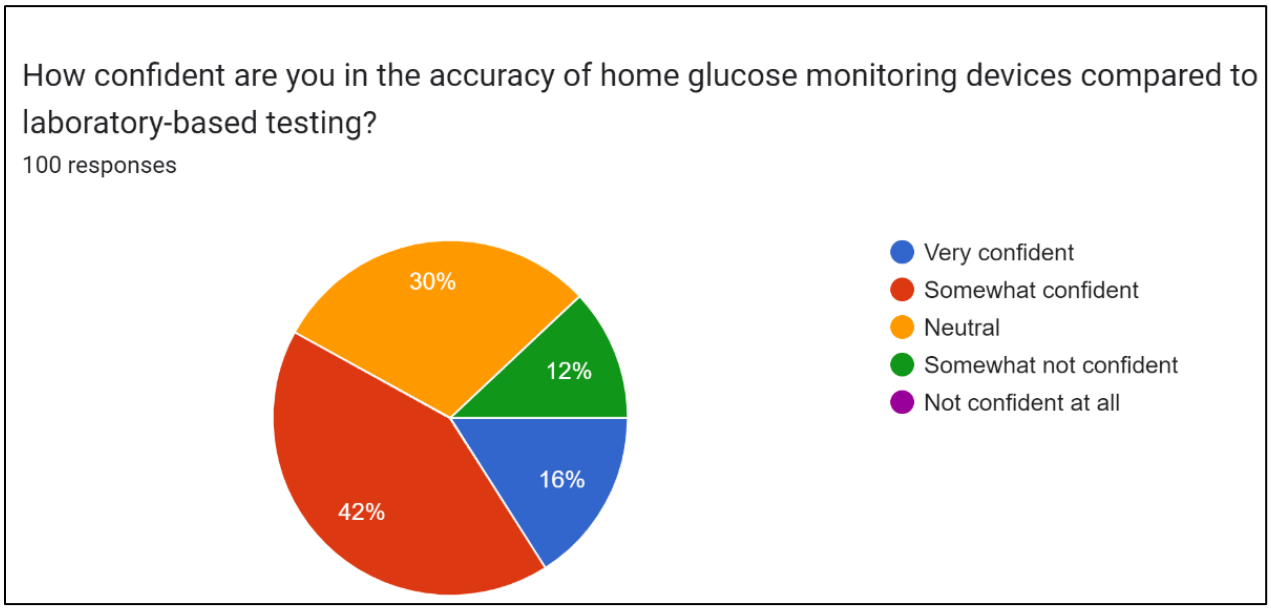
I. Factors Influenced in monitoring Glucose level at Home



Interpretation:

The major driver to use home glucose testing method was due to doctor's recommendation which has 72% respondents. 59% reported that glucometers bring them peace to mind knowing their regular blood glucose levels and this helps them to make conscious decisions on their lifestyle and food habits. 52% reported that glucometers are indeed cost-effective method than to laboratory testing for which they prefer this method. 42% agreed to the accuracy and reliability o the test results of the glucometers as this also gives them a sense of autonomy over their or their patients' diabetic condition. Therefore, the top reasons to come out or the factors which push consumers to use glucometers to monitor their glucose levels in their blood are 1. Doctor's recommendation 2. Getting peace at mind and 3. Glucometers are cost-effective method.

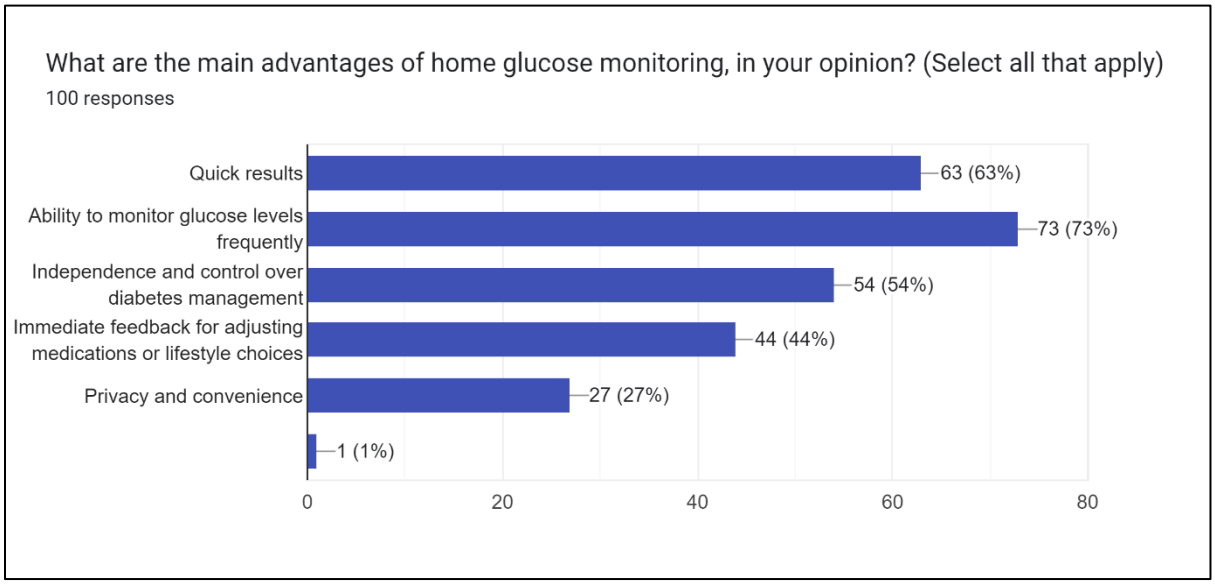
J. Confidence Level of using home glucose monitoring Device



Interpretation:

The maximum percentage of respondents i.e., 42% are not very confident and cannot put much faith on home glucose testing when they have to compare them to laboratory-based testing. The sample is often taken from a vein in your arm and processed to eliminate red blood cells so that only the plasma is analyzed in a lab test run by healthcare professionals which gains more faith from people doing at home.

K. Opinion of Advantage of using home glucose monitoring



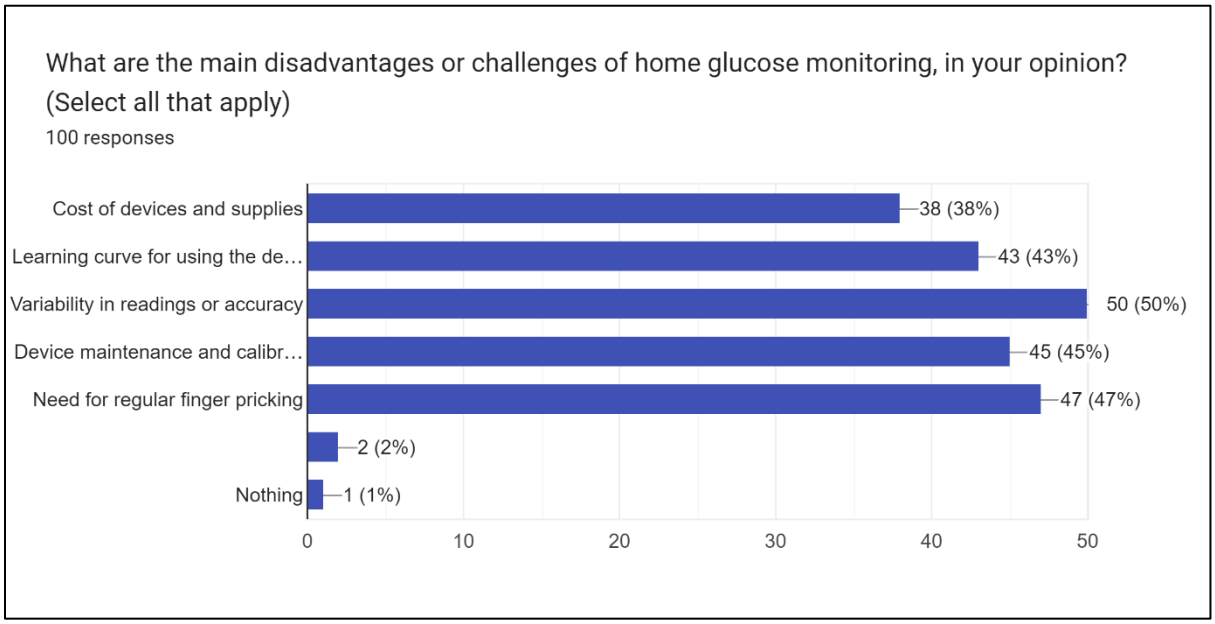
Interpretation:

The top results for which home glucose testing has proven to be advantageous to the respondents are.

1. Ability to monitor glucose levels frequently.
2. Quick results
3. Independence and control over diabetes management

As a patient to have a continuous knowledge of the glucose levels help in taking better decisions for their body. They have the sense of autonomy, and they can do their reading in their personal space and time. Glucometers have proven to be convenient for most part. There are its certain disadvantages yet in order to have an upper hand in diabetes care management in the care continuum glucometers play a significant role.

L. Opinion of Disadvantage of using Home glucose monitoring



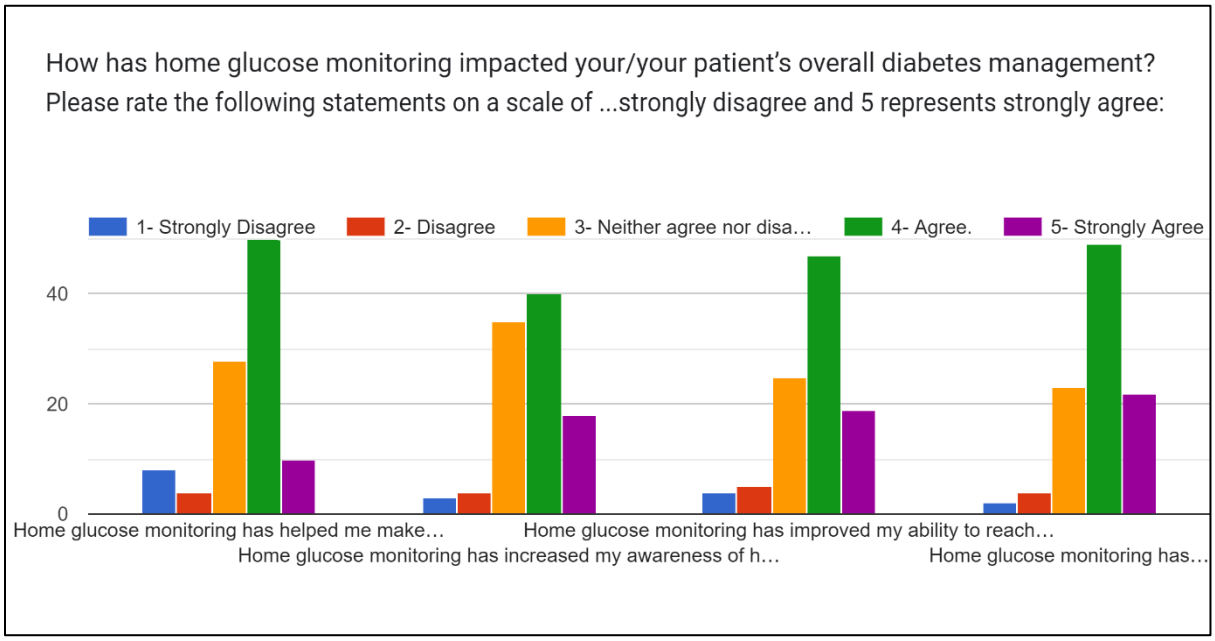
Interpretation:

The top listed disadvantages found out of glucometers are:

1. Variability in readings or accuracy (50%)
2. Need for regular finger pricking. (47%)
3. Device maintenance and calibration (45%)
4. Learning curve for using the device (43%)

It can be understood as Glucometers have been reportedly painful which creates a psychological barrier from the patients end to use it regularly. Along with this, patients not following fasting procedures properly leads to variability in reading or accuracy. Without proper knowledge of its use due to its finger pricking method, it can lead to infection as well as diabetic patients are more prone to infections. It also needs its battery changed and careful preservation from moisture to maintain its durability which can be difficult especially for patients falling in an older age group.

M. Impact of home glucose level monitoring on Patents' diabetic management



Interpretation

a) Home glucose monitoring has helped me make better treatment decisions. Almost 50% has agreed to this statement.

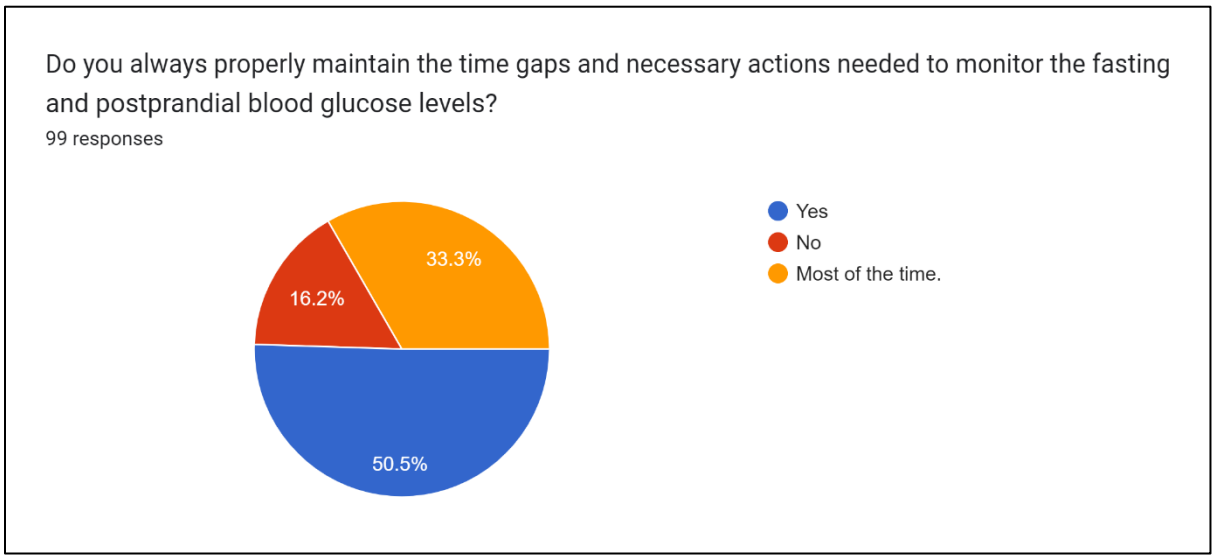
b) Home glucose monitoring has increased my awareness of how my body responds to different foods and activities. 40% agreed to this statement.

c) Home glucose monitoring has improved my ability to reach and maintain target glucose levels. Around 43% agreed to this statement.

d) Home glucose monitoring has positively influenced my motivation to manage my diabetes. 49% agreed majorly to this statement.

In conclusion, home glucose monitoring have had quite a positive impact in overall diabetes management.

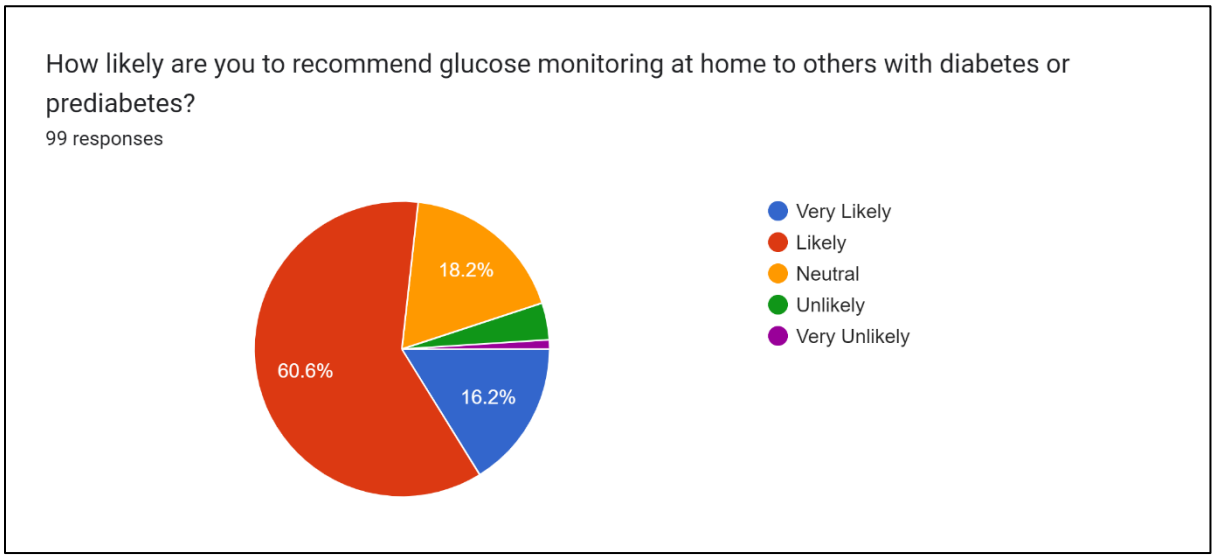
N. Experience on Time-Gap for monitoring glucose level



Interpretation:

While most respondents almost 50% said that they maintain the necessary gaps and fasting measures yet there was another 50% who doesn't follow it or are inconsistent with following the necessary measures. This is a concerning situation as not following the measures will automatically lead to variability and reliability issues in the glucometer readings thus affecting the healing process of the patient and lessen down their autonomy over the process. They will also lose faith in home glucose testing due to wrong readings.

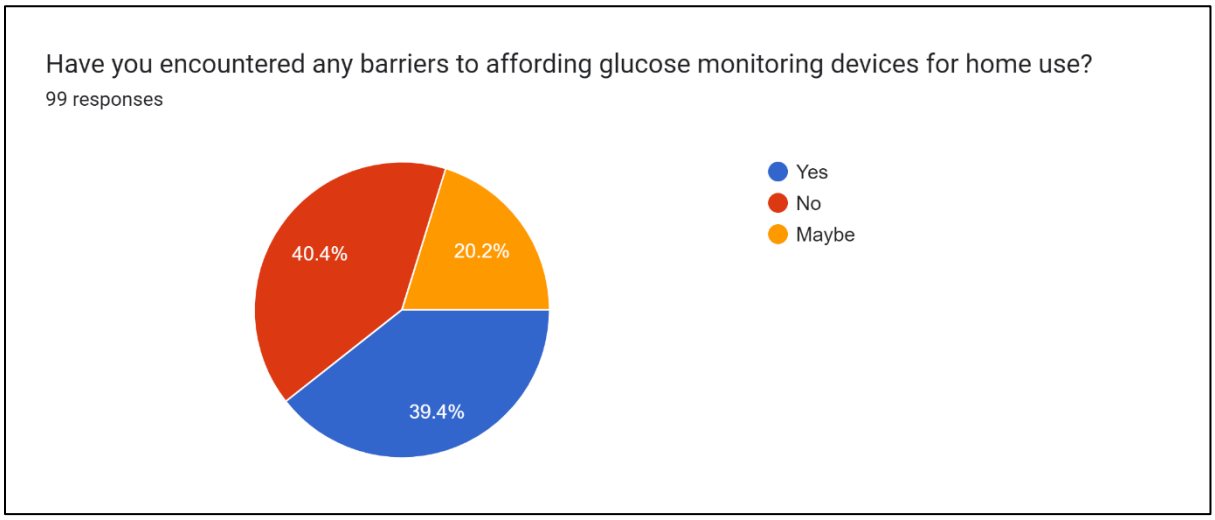
O. Recommendation on use of glucose monitoring at Home



Interpretation:

60.6% respondents are likely to recommend glucose monitoring using devices like glucometers to other followed by 16% who are very likely going to recommend its use. It shows the convenience people face with glucometers which will prompt them to recommend the devices to others.

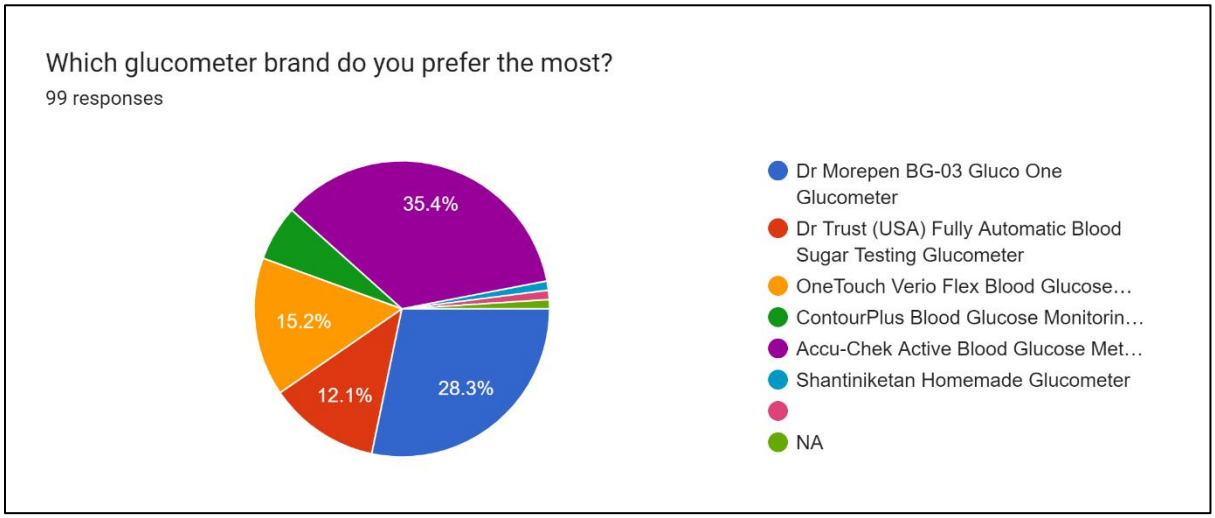
P. Barriers of affording glucose monitoring at home



Interpretation:

While 40% respondents have not faced any issues in terms of affordability of home glucose testing kits, but alarmingly 39% of respondents reported to have an issue in terms of affordability. Since it is a regular use product, for people coming from lower socio-economic background might face an issue in affording the devices and more so the test strips which needs to be kept replacing regularly.

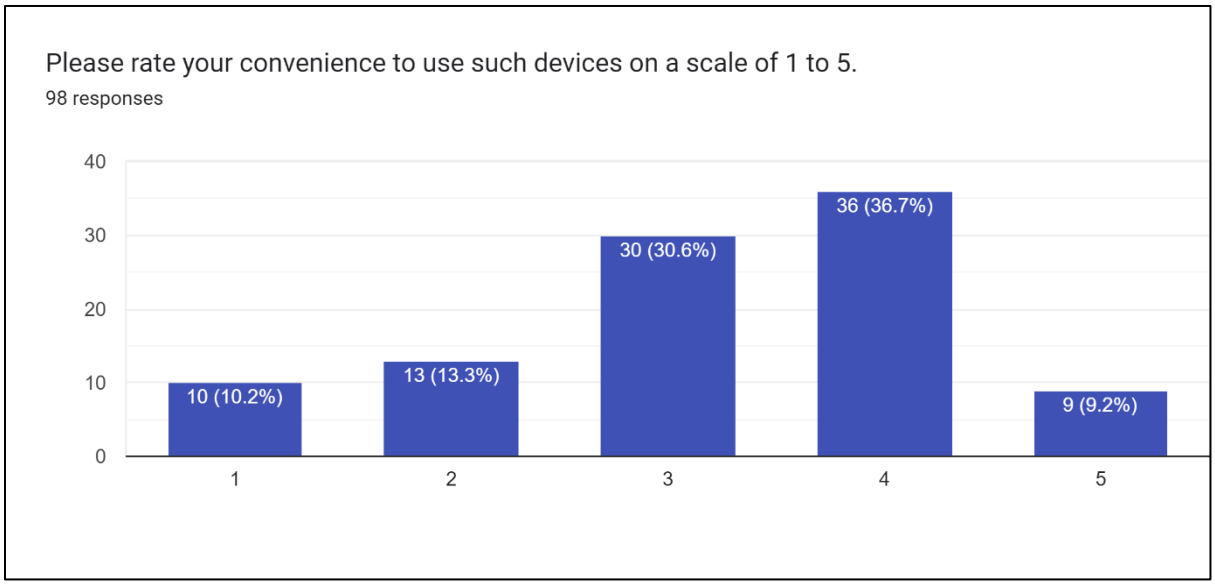
Q. Preferable Brands of Market-available Glucometers



Interpretation:

The most used glucometer was found out to be Accu-check Active Blood Glucose meter. Followed by Dr Morepen BG-03 Gluco One Glucometer. A 2023 list of glucometers used in India was used to jot down the most used glucometers (refer literature review section). Accu-check has proven to be very useful because its Test Time is just Five seconds, Blood Sample Size is 1.5 microliter, has 10 test strips and 10 lancets and does not have a manual coding and stores up to 500 test results in its memory.

R. Convenience of Using Glucometer



Interpretation:

It was found out that only 5% of the respondents found the glucometers extremely convenient to use. The maximum percentage of respondents that is almost 37% are still to some extent struggling. It shows their lack of dexterity when it comes to devices that respondents are using on a daily basis.

Chapter 5: Recommendations

Diabetes education has to be better monitored and implemented. With better methods the people suffering from diabetes and their caregivers both can be active participants in better diabetes management platform. Both the parties need to be made aware of all the complications and the available methods to deal with diabetes. There has been negative attitude towards diabetes which can be addressed through better counselling and will also enhance the self-monitoring skills. Education has been found out to be an important factor in better management of treatment procedure of diabetes. In fact, taking proactive steps in spreading awareness regarding the condition has evidence to have been very successful in modifying behaviors, like more compliance to the treatment mechanism which in turn decreases the complications in diabetes.[9] Education needs to be very comprehensive, and it should include the wide range of knowledge on diabetes like risk factors, complications, diet control, physical activity, regular checkups, and screening.

The National Programme for Control of Diabetes, Cardiovascular Disease, and Stroke is being brought into action and this program has a very high potential to increase the level of awareness regarding diabetes holistically. For physicians (Certificate Course in Evidence Based Diabetes Management [CCEBDM]) and for diabetes educators (National Diabetes Educator's Programme [NDEP]) have been important initiatives by the government which has proven to be advantageous in capacity building process. The Public Health Foundation of India and Dr. Mohan's Diabetes Education Academy (DMDEA) collaboratively launched the first programme, CCEBDM, in order to enhance overall patient treatments by providing professional healthcare persons' evidence-based advice. The aim has to have It just needs to keep a multidisciplinary approach to the programme.[9]

Respondents complained of its affordability which can be addressed with strengthening medical device reimbursement policies. Patients have showed concern regarding variability in readings which can lead to lesser faith in home glucose testing, but it was also seen that patients also do not follow all necessary fasting rules before testing which leads in reading variability. Patients need to have a proactive approach towards incorporating the glucose testing in their lifestyle

seriously which can help them in this. It has been understood that finger picking has been a hassle and has led to a hesitant nature in adopting regular finger pricking. Studies show that companies around the world have come up with efficient alternatives to address the issue. They have introduced noninvasive methods of glucose monitoring. There have been questions about its accuracy when compared with traditional test strips. There have been other non-invasive methods found now like Google Contact lens which is still to come to market but it can measure glucose levels through tears of eyes. German company DiaMonTech created a monitor which uses infrared laser through skin to detect sugar levels. Eversense developed a subcutaneous implant which needs to be surgically done by doctor and it's a one-time thing. It uses transmitter to do the readings from under the skin. NovioSense created a monitor which has to be used by placing it under the lid. The monitor has a metal coil with nano sensors which sends the data to a smartphone.[18] Continuous glucose monitoring system (CGMS) is a technology that has revolutionized diabetes management. It is a small device that is placed on the skin and measures glucose levels in the interstitial fluid every few minutes. CGMS has been widely accepted and used in developed countries for several years, but its acceptability in the Indian population is still a subject of debate due to lack of awareness and the systems being very expensive.

India needs to adopt and adapt to these dynamic changes in the Diabetic medical device space in order to be at par with the rest of the world and also to ease the diabetic care platform for the patients in India. When it comes to affordability, one of the best products in market is the FreeStyle Libre Glucose Monitoring system by Abbott which is priced at Rs. 10429 (Amazon price) which is a lot. Indian medical device industry needs to keep the Indian socio-economic background in mind and try to develop something similar to the FreeStyle Libre at a much affordable price range.

Chapter 6: Conclusion

Patients suffering from chronic condition like diabetes must be serious for their day-to-day care. They need to engage in regular monitoring oral medications, managing weight and stress, maintaining physical exercise, managing nutrition, and, if necessary, they also need to use insulin via injections or pumps. Medication adherence has been a real issue over time which patients themselves need to take more serious approach towards. The major stakeholders in this condition are considered to be the patient themselves therefore the onus is on them to be self-aware and hone the self-monitoring skills at home. They need to be active participants in the decision-making process to lead to better diabetic care management process. How people will perceive the home testing kits stems from how doctors or healthcare professionals guide them through the process or sensitize them to home glucose testing kits and procedure. They also need to add value to their prescription as they need to take into consideration of patients' clinical as well as socio-economic background before recommending the frequency and methods of usage of home glucose testing kits to diabetic individuals who are not on insulin.[10]

In order to improve patient outcomes and manage diabetes holistically a complex multidisciplinary approach is needed. Proper monitoring of diabetes on a regular basis is needed to understand the effects of hypoglycemia and hyperglycemia. A systematic approach needs to be implemented where there has to be a collaborative approach from the consumers, endocrinologists, diabetes nurse educators, clinical nurse specialists, dieticians, pharmacists and data analysts to manage diabetes as a menace to the society.[11]

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APPENDIX: 1

Questionnaire on Perception among Indian regarding Home Glucose Level Monitoring

Gender :	Male Female	Age:	
2. Which zonal region of India do you belong to?			North/West/East/South
3. Are you a caregiver to a diabetic patient or a patient yourself?			Patient/Caregiver/Other
4. How long have you been monitoring your/patient's glucose levels at home?			
a. Less than 1 year	b. 1-3 years	c. 3-5 years	D. More than 5 years
5. What brand of glucometer are you/ your patient using?			Dr Morepen BG-03/ Accu-Chek Active/ OneTouch Verio Flex/ AccuSure/ OneTouch Select Plus Simple/ Other / state the other
6. Are you aware of necessary steps involved to conduct home glucose monitoring test with the necessary test kits?			
Yes	No	Somewhat	
6. Are you aware of all the available methods of home glucose testing available in India?			
Yes	No	Somewhat	
7. What is your perception of home glucose monitoring? (Please rate the following statements on a scale of 1 to 5, where 1 represents strongly disagree and 5 represents strongly agree):			
a) Home glucose monitoring is convenient.			1 – 2 — 3— 4 – 5
b) Home glucose monitoring helps in better diabetes management.			1 – 2 — 3— 4 – 5
c) Home glucose monitoring makes me/patient skeptical due to the finger prick method.			1 – 2 — 3— 4 – 5
d) Home glucose monitoring is accurate and reliable.			1 – 2 — 3— 4 – 5
e) Home glucose monitoring saves time and effort.			1 – 2 — 3— 4 – 5
f) Home glucose monitoring is a burden			1 – 2 — 3— 4 – 5
8. What factors influenced your decision to monitor glucose levels at home? (Select all that apply)			
a) Doctor's recommendation			
b) Peace of mind with the knowledge of my/patient's glucose levels			
c) Accuracy and reliability with autonomy			
d) Cost-effectiveness			
e) Lack of access to healthcare facilities			
f) Genetics and age factors			

9. How confident are you in the accuracy of home glucose monitoring devices compared to laboratory-based testing? (Please mark ✓)				
a) Very confident				
b) Somewhat confident				
c) Neutral				
d) Somewhat not confident				
e) Not confident at all				
10. What are the main advantages of home glucose monitoring, in your opinion? (Select all that apply)				
a) Quick results				
b) Ability to monitor glucose levels frequently				
c) Independence and control over diabetes management				
d) Immediate feedback for adjusting medications or lifestyle choices				
e) Privacy and convenience				
f) Other (please specify)				
11. What are the main disadvantages or challenges of home glucose monitoring, in your opinion? (Select all that apply)				
a) Cost of devices and supplies				
b) Learning curve for using the devices				
c) Variability in readings or accuracy				
d) Device maintenance and calibration				
e) Need for regular finger pricking				
f) Other (please specify)				
12. How has home glucose monitoring impacted your/your patient's overall diabetes management? Please rate the following statements on a scale of 1 to 5, where 1 represents strongly disagree and 5 represents strongly agree:				
a) Home glucose monitoring has helped me make better treatment decisions.				1 – 2 — 3— 4 – 5
b) Home glucose monitoring has increased my awareness of how my body responds to different foods and activities.				1 – 2 — 3— 4 – 5
c) Home glucose monitoring has improved my ability to reach and maintain target glucose levels.				1 – 2 — 3— 4 – 5
d) Home glucose monitoring has positively influenced my motivation to manage my diabetes.				1 – 2 — 3— 4 – 5
13. Do you always properly maintain the time gaps and necessary actions needed to monitor the fasting and postprandial blood glucose levels?				
Yes		No		Most Times
14. How likely are you to recommend glucose monitoring at home to others with diabetes or prediabetes?				
Very Likely	Likely	Neutral	Unlikely	Very Unlikely
15. Please rate your convenience in using such devices on a scale on 1-5.				
16. Have you encountered any barriers to affording glucose monitoring devices for home use?				
Yes			No	