THE UNIVERSITY OF THE WEST INDIES

Faculty of Medical Sciences

DM in Family Medicine

A Cross-Sectional Study: Client's Satisfaction with Chronic Disease Generic Medications at Primary Healthcare Institutions.

Student Name and ID:

Sarah Saira Sampath- 00732412

CLASS OF 2020

Blank Page

ABSTRACT

Background: Client's satisfaction with their medication is defined as, *"the client's evaluation of the process of taking the medication and the outcomes associated with the medication."* The procurement and supply of medications to manage chronic diseases amongst a country's citizens is a major concern. Generic drugs were formulated as one of the mechanisms of minimising healthcare costs without compromising the access to quality healthcare. Generic drugs are drugs that are manufactured to have similar characteristics as their brand-name counterpart(s). The objective of this research study was to determine how satisfied were primary healthcare clients with the use of generic medications in the management of their chronic-disease conditions. Secondary analysis was also performed to evaluate the percentage of chronic-disease clients who were at higher risk of being non-adherent with their pharmacological treatment.

Method: A randomised, cross-sectional study design was performed. Clients were interviewed and administered the survey at selected chronic disease clinics under the Arima cluster of the North Central Regional Health Authority (NCRHA) of Trinidad and Tobago. Specific chronic-disease conditions were targeted in this research study.

Results: Hypertension (80.6%) was found to be the most common chronic disease suffered by most participants. Of the 470 participants, the treatment satisfaction with chronic-disease generic medications was calculated to be an average of 66, with the values for this scale ranging from 0 to 100. Secondary analysis revealed that 51% of the participants were at a higher risk of being non-adherent with their pharmacological treatment.

Conclusion: The role of the healthcare professional in providing education to chronic disease clients not only about their medical conditions, but also about their pharmacological treatment, especially the advantages of chronic disease generic medications, is of utmost importance in alleviating hospitalisations, poor health outcomes and financial constraints. Health education can also aim to further reduce the risk of medication non- adherence.

Key words: Client's Satisfaction; Generic drugs; Chronic diseases; Treatment Satisfaction; Medication Non-adherence

ABBREVIATIONS

North Central Regional Health Authority	**NCRHA**
World Health Authority	**WHO**
Chronic Non-Communicable Disease	**CNCD**
Diabetes Mellitus	**DM**
Health Related Quality of Life	**HRQL**
Chronic Disease Assistance Program	**CDAP**
Treatment Satisfaction Questionnaire for Medication	**TSQM**
Medication Adherence Scale	**MAS**

LIST OF FIGURES

LIST OF TABLES

TABLE OF CONTENTS

INTRODUCTION

The purpose of this evaluative research by adopting a cross-sectional study was to determine if primary healthcare clients (patients) are satisfied with the use of generic medications (drugs) to manage their chronic disease condition(s). It was found that there were some clients who were reluctant in accepting generic medications and would prefer to use the original drug counterpart. [1] However, original and/or brand-named medications are generally costly and not commonly available at public primary healthcare institutions in Trinidad and Tobago.

However, this non-acceptance dilemma is not only unique to Trinidad and Tobago because Ganter and Kreling (1996) found that some US clients perceived that there were risks associated with taking generic medications. [2] The 1995-study conducted in Central Wisconsin, USA revealed that most of the clients found that there was a greater risk in taking generic medications for cardiovascular conditions in comparison to taking it (generic medications) to treat a streptococcal throat infection. However, they did indicate that the lack of knowledge and/or education does have a negative impact on generic medication usage. [2]

Thus, this research study ascertained what factors (variables) contributed to clients' satisfaction with generic medications; particularly, clients' knowledge and attitudes associated with the use of generic medications in selected primary healthcare institutions within NCHRA. This research study provided a brief overview of the local public healthcare system and the management of chronic diseases; the rationales for the use of generic medications in the local public healthcare system; and discussed the pharmaceutical aspects of generic medications. The author also reviewed numerous academic literature, both local and international, to analyse clients' satisfaction with medications.

Hence, the reviewed literature provided support for this research study based on recognized and published theoretical concepts and perspectives. The remaining aspects of this research study discussed the various aspects of the research study design and methodology the author adopted having reviewed various studies that researched the similar topic of interest. The research findings from this study can help edify both healthcare professionals and clients/patients and improve the local primary healthcare system.

RESEARCH BACKGROUND

Escalating healthcare expenses remain a serious concern for public healthcare systems worldwide (WHO 2004). [3] The World Health Organisation (WHO) reported that in many developing countries, 80% of their national expenditure is attributable to public healthcare expenditures. [3] Particularly, the procurement and supply of medications to treat and/or manage chronic diseases amongst its citizens. Moreover, these governments are challenged by the need to minimize healthcare costs without affecting the quality of healthcare delivery. [4] Thus, a public healthcare system with limited resources and one that has to service a large population, may resort to dispensing generic medicines. This budgetary initiative finds a balance in reducing national healthcare expenditure and providing quality public healthcare services. [5]

This study focused on selected health centres within the primary healthcare region of North-East Trinidad under the administration of the NCRHA as the target population. The targeted primary healthcare clients that were studied were those receiving medical management for their chronic non-communicable diseases (CNCDs). A governmental evaluation conducted in 2007, *"Port of Spain Declaration on CNCDs"* showed that CNCDs are significant causes of morbidity and mortality both locally and internationally. The prevalence of diabetes has not only doubled locally but also globally, whereas hypertension still remains the leading risk factor for mortality worldwide. The 2007-study also found that mortality in the Caribbean from CNCDs is the highest in the Americas. 40% of those CNCDs-related deaths were premature and could have been prevented; mainly, heart attacks, cerebrovascular disease (stroke), and diabetes. [6]

Primary Healthcare Management of Chronic Disease Conditions

Generally, chronic-disease clients require polypharmacy in the management and/or treatment of their medical conditions. However, due to the various types of chronic diseases and the myriad of medications (both generic and original/brand-named), the research focused mainly on the following selected chronic diseases: *Diabetes Mellitus (Type 2 DM), Hypertension, Dyslipidaemia, Cardiovascular disorders, Cerebrovascular disease and Asthma*. Therefore, clients' satisfaction with generic medications was evaluated in these aforementioned chronic diseases.

Clients' satisfaction was assessed with the use of specified domains of: *'symptom relief/efficacy, side effects, ease and convenience, general satisfaction and cost.'* Clients' knowledge and attitude regarding the use of generic medications were also assessed, as a lack of knowledge can be attributed to the non-acceptance of generic medications and as well can impact on clients' satisfaction as well.

The findings from this research study would help to further minimize the 'knowledge deficit' that clients may have towards the use of generic medicines in managing their chronic disease(s). Furthermore, the research study also examined if clients' satisfaction influenced the risk of non-adherence by the sample, especially since medication adherence/compliance contributes to an enhanced health-related quality of life (HRQL) for chronic-disease clients and detecting medication non-adherence is a challenging task especially in chronic disease clients in clinical practice.

Original/Brand-named Medications versus Generic Medications

The Food and Drug Administration (FDA 2018) classifies, *"a brand-named or original drug is a new medicine that was discovered, developed and marketed by the founding pharmaceutical company; and a generic drug that has similar characteristics to an original or brand-named drug in regard to its main ingredients, the strength of the drug, the dosage form, therapeutic use, safety instructions and the performance and quality of the medication."* [7]

According to Stuart *et al* (2017), these researchers described generic medications as, *"medicinal products that have been produced after the patent expiration of the innovator (brand-named/original) drug for sale…these generic drugs are usually manufactured similarly to the innovator drug with regards to their dosage form, dose/strength, indication, drug performance and most importantly, active ingredients."* [1]

Generally, the founding pharmaceutical company files for a patent to protect this newly-discovered drug against other pharmaceutical companies reproducing and selling the same type of drug. However, the patent lifespan for a specific drug may last up to 20 years depending on the rules and regulations of the country in which the patent application was made. Thus, a generic drug (medication) can only be manufactured and distributed by another pharmaceutical company when the patent expires for the original/brand-named medication. [8] Despite this long waiting period, the supply and availability of generic medications dominate the pharmaceutical markets worldwide.

Nevertheless, for a generic drug product to be approved, it must satisfy stringent standards established by the FDA in the following areas: *identity, strength, quality, purity and potency in similar comparison to the original/brand-named medication.* [8] Consequently, a typical generic drug product should be the bioequivalence of that of an original/brand-named medication before it is manufactured and distributed. [9,10] The international standard for bioequivalence of a drug is, *"the mean maximum concentration attained, the period at which that concentration is attained, and the area below the concentration – the*

time curve for the generic drugs falls within 80%- 125% of the brand-named/original medications, when administered with a fed or fasting state," (US- FDA 2017). [9, 10]

Notwithstanding the bioequivalence requirement, there is a significant difference between generic and original/brand-named medications. It has been reported that the average price/cost of a generic medication is 20% to 80% lower than the original/brand-named medicinal product. The price reduction is furthered propelled by various competing generic companies to manufacture and distribute a similar generic drug product for specific medical conditions (diseases). [11, 12]

Conversely, what accounts for a higher-priced original/brand-named medication, is the significant amount of research and funding that goes into the development of the new drug. Extensive studies are undertaken to prove the efficacy and safety of the newly-discovered drug. This research and development process can take several years with an approximate cost of $1.1 billion (USD). [13] Unlike the founding pharmaceutical company, generic drug companies do not have to make such large investments to bring their version of a drug to the market. This does not mean that the generic medication is of lower quality or have been produced using a substandard manufacturing process. However, it is likely that the preparation between the original/brand-named drug and the generic counterpart may differ somewhat. [14, 15]

Hence, it is these minor differences such as the impurities in the excipients used in the drug preparation of generic medications that can result in unforeseen harmful effects on drug absorption, bioavailability, efficacy and safety. [16, 17] Meyer and Rosenbaum *et al.*, (2001, 1994) reported that many generic medications, for example, generic versions of Tegretol and Dilantin, had to be withdrawn from the market due to clinical trial failures and the bioequivalence of the generic drug products did not satisfy regulatory standards. [18, 19]

Within the domestic pharmaceutical industry, the Chemistry, Food and Drug Division (CFDD) under the purview of the Ministry of Health in Trinidad and Tobago only regulates the provision of drugs/medications by ensuring a safe quality of an equitable standard for use. [20] Thus, the CFDD is guided by established international regulatory standards; particularly, since there are no large pharmaceutical manufacturers based locally. In Trinidad and Tobago, there are mainly, drug distributors and/or franchise holders for international pharmaceutical companies such as, but not limited to: *Pfizer, GlaxoSmithKline, Merck & Co, Sanofi, Novartis, AstraZeneca,* etc.

Despite the rigid regulatory framework to manufacture and distribute generic medications, it has been observed that these generic drugs are underutilised and/or not accepted by some clients in local health centres. Moreover, knowledge and/or awareness regarding generic medications amongst clients/patients is not well researched in developing countries such as Trinidad and Tobago. Hence, this research study addressed this subject area.

An Overview of Client Satisfaction

For this research study, a client was referred to as, *"an individual who either purchases or consumes a medication for the purpose of management/treatment of his/her specified chronic disease condition."* [21] It has been found that mainly pharmaceutical companies analyse clients' satisfaction with medication use. These pharmaceutical companies recognize the client as a valued consumer and are desirous in obtaining feedback to improve their products. For example, if the particular drug has a problematic packaging or is produced in a cumbersome dosage form, these issues/problems can contribute to decreased clients' satisfaction with this medication. Thus, effective use of client feedback can assist pharmaceutical companies to reformulate drugs or provide simple packaging for easier drug administration and consumption. [21]

It should be distinguished that client's satisfaction can be evaluated within three themes: *satisfaction with the healthcare delivery system, treatment satisfaction, or satisfaction with medication.* [21] Hence, this research study differentiated satisfaction with medication from other aspects of the client's satisfaction. Satisfaction with medication entails the individual (client) judging the drug from the initial phase of consumption to the final phase of attaining the anticipated effects associated with the medication. [21]

Additionally, clients' satisfaction with medication can be further analysed using the psychometric domains of *symptom relief/efficacy, ease and convenience, side effects, impact on health-related quality of life (HRQL), general satisfaction and cost* of the generic medications. [21] For the purpose of this research study, the author (researcher) evaluated clients' satisfaction using those psychometric domains with the use of generic medications in chronic-diseased clients.

Notably, the effect of medication not only impacts on the symptoms relevant to that specific disease, but it can also cause side effects and/or adverse effects that are unwelcomed by the client. Thus, if the client notices these unwanted effects (side effects/adverse effects) associated with the mode of action of the drug, it is likely that the client's satisfaction with the medication would decrease. More importantly,

when the symptoms of the disease are affected (negatively or positively) by the medication itself, then this domain (symptom relief) can influence the HRQL and the overall functional status of a client. [21]

The author (researcher) opined that there was a great importance of evaluating a client's satisfaction with their generic medications. Particularly, to determine if clients' satisfaction with medication is related to medication adherence. Low adherence with prescribed medical interventions remains an ever-present and complex problem in treating/managing chronic-diseased clients locally. Unfortunately, there is no gold standard and/or benchmark available for the measurement of adherence and there are limited research studies that examine a relationship between medication satisfaction and medication adherence, especially with generic medications. [21]

As previously mentioned, this research study evaluated what was the relationship between clients' satisfaction with generic medications and medication adherence with their prescribed treatment regimen. The research findings on the relationship of clients' satisfaction with medications and medication adherence would assist healthcare professionals (doctors and nurses) in educating clients about the use of generic medications. Both nurses and doctors as healthcare professionals share the responsibility for patient education. However, primarily doctors are responsible for teaching clients about their medical conditions and highlighting their pharmacological treatment. Whereas nurses are generally the first point of contact to establish the nurse-patient relationship and equally responsible for educating and supporting clients in their medical conditions and the importance of being adherent with their treatment. Thus, the more-informed or more knowledgeable clients are about generic medications can change their attitudes towards the use of these generics in the management of their chronic diseases. Ultimately, once clients' can effectively manage their chronic diseases, this would reduce the existing, heavy burdens that are placed on the public healthcare system and/or prevent or reduce premature deaths (CNCDs-related mortality).

PROBLEM STATEMENT/NEED ASSESSMENT

A problem statement is generally one or two sentences which explain a problem, an issue, or a negative situation for which the research study intended to address. For this research study, the following was the proposed problem statement:

Problem Statement: ***It is observed that primary healthcare clients are reluctant and/or refuse to accept generic medications in the management of their chronic disease(s).***

A preliminary, informal investigation through conversations with some clients highlighted various issues/problems regarding generic medications, for example:

- Some clients have heard that generic medications have *'poor safety and effectiveness'* and based their decisions on those unfounded comments/opinions.
- Other clients complained that *'it doesn't work'* or know of individuals who had similar complaints.
- Some clients refer to generic medications *'as cheap drugs that sometimes work.'*
- Some clients were dissatisfied with some of the side effects.
- Some clients did not know that they were using generic medications and therefore, did not know that there was an original/brand-named counterpart.

Alternatively, there were some clients who were satisfied with the price of the generic medications because of their socioeconomic status and there were some who didn't have an issue using the generic medications.

Based on the above-informal findings, there was a need to further investigate what are the contributing factors for those clients' reasoning. Additionally, given the contrasting views of those clients, this formal study aimed to determine how many clients were satisfied with generic medications. Furthermore, did their satisfaction levels impact on the management of their chronic diseases? Therefore, it was opined that if clients were satisfied with the use of the generic medicines in the management of their chronic-disease conditions, then the financial costs placed on the State (economy) and individuals would be significantly reduced; especially, if there exists a relationship between clients' satisfaction with their medication(s) and adherence with their prescribed regimen *(course of prescribed medications).*

RESEARCH QUESTIONS

The following questions were addressed and/or answered upon completion of this research study. The researcher/author subdivided the research questions into primary and secondary questions.

***Primary Research Questions**:*

1. How satisfied are primary healthcare clients with the use of generic medications in the management of their chronic disease condition (s)?

***Secondary Research Questions**:*

1. What proportion of clients are using generic medications to manage their chronic disease conditions? ***(Appendix F, Fig 14)***

2. What factors of generic medication/s contributed to overall clients' satisfaction?

3. What factors of knowledge about generic medications contribute to overall satisfaction? ***(Appendix F, Table 8- linear regression table)***

4. What proportion of primary healthcare clients are at increased risk of being non-adherent with their prescribed chronic-disease medications?

5. Does clients' overall satisfaction influence or impact on their risk of medication non-adherence?

RESEARCH STUDY OBJECTIVES

The following objectives were addressed in this research study:

1. To ascertain the reasons for primary healthcare client's non-acceptance and/or usage of generic medications.

2. To identify what proportion of clients' polypharmacy is generic medications.

3. To establish if generic medications have a positive and/or negative impact on the management of the selected chronic diseases.

4. To determine clients' satisfaction with generic medications using established psychometric domains.

5. To identify if there exists a relationship between clients' satisfaction and the risk of medication (drug) non-adherence with the use of generic medications.

AIMS OF RESEARCH STUDY

The following aims were also addressed in this research study:

1. To investigate if the non-acceptance and/or usage of generic medications has an impact on the management of chronic diseases.

2. To determine the proportion of clients that are using generic medications to manage their chronic disease conditions.

3. To highlight and discuss the background knowledge and attitudes that clients may have with the use of generic medications in the management of their chronic disease conditions. ***(Appendix F, Tables 8 and 9)***

4. To identify and explain what factors contribute to clients' satisfaction with generic medications?

5. To determine if the clients' satisfaction with generic medications influences the risk of medication non-adherence.

LITERATURE REVIEW

There are voluminous research studies and literature that examines clients' satisfaction in diverse disciplines. However, applicable literature on clients' satisfaction with medication is somewhat limited both locally and internationally. Nonetheless, the researcher was guided by suitable theoretical perspectives and concepts to ascertain clients' satisfaction with medications; the advantages and disadvantages of generic medications; effects of generic medications in comparison to original/brand-named medications and the impact generic medications has on the management of chronic diseases; particularly healthcare costs and drug adherence/compliance.

The research method adopted to obtain the following literature was attained mainly via the Internet. Google was used as the main Internet search engine and methodically, various key terms were entered and searched, such as but not limited to, *clients' satisfaction, generic medications, original medications, primary healthcare issues, chronic diseases and so on.* Additionally, virtual libraries and websites such as *Google Scholar, Pubmed, SAGE journals, Wiley Online Library, Research Gate, Science Direct, Academia Journals and the US National Library of Medicine* provided appropriate academic materials/journals and published articles/studies to produce the literature review herein. These websites were chosen based on their academic creditability and found to be technologically safe and secured. Unfortunately, most of the literature obtained were mainly international journals/articles due to the limited research studies published locally and/or local studies were not easily available or obtainable via the Internet.

Clients' Satisfaction with Healthcare Services

According to WHO (2000, p.8), *"client satisfaction with the medical-treatment process may influence, and/or be influenced by, the outcome of the medical treatment…It is advisable to recognize the evidence of positive client satisfaction associated with the quality and effectiveness of medical treatment.* [22] Joseph and Nichols (2007) postulated that patient (client) satisfaction and the quality of life are considered central elements in healthcare management. They further stated that modern healthcare systems are modified to provide a client-oriented approach in delivering healthcare services. [23] Thus, client satisfaction is an important predictor of morbidity, mortality and adherence/compliance with medical treatment.

Furthermore, Joseph and Nichols (2007) considered client satisfaction to be a multidimensional framework that encompasses all aspects of healthcare services, healthcare facilities, the availability and

convenience of healthcare and budgetary requirements. [23] However, client satisfaction is not only limited to general healthcare, but it applies to the extent that condition-specific needs are met.

Thus, the overarching goal of healthcare treatment/management is to improve and maintain the health status of a client. However, it is important that healthcare professionals recognize clients' views and opinions because it is not only important in evaluating healthcare delivery but also assessing the client's overall health. More importantly, satisfied clients are more likely to adhere or comply with prescribed medical management, (Aharony and Strassar 1993). [24, 23]

Clients' Satisfaction with Generic Medications

As previously mentioned, there is a paradigm shift in healthcare delivery within the public primary healthcare system. For example, in 2003, the Trinidad and Tobago Government developed and implemented a Chronic Disease Assistance Programme (CDAP) to reduce overcrowding in public healthcare pharmacies and to increase the availability of free medications to clients throughout Trinidad and Tobago by co-opting private pharmacies. CDAP is just one of the state's healthcare initiatives to effectively manage chronic diseases for the populace of Trinidad and Tobago. In addition to CDAP medications, primary healthcare clients can access additional chronic-disease specific medications free of charge at various public healthcare institutions. These governmental measures are in keeping with WHO's directive that *essential medicines should be easily accessible and affordable*. [25] Therefore, the government ensure that generic medications have been widely available at the public health centres for the past ten (10) years.

However, due to economic constraints and procurement challenges experienced by the Trinidad and Tobago Government, there is often a deficit in the medication stock/supplies and/or only generic medications are available at public healthcare institutions. Generic medications are commonly used both in public and private healthcare systems internationally because of their cost-saving benefits. In a Malaysian study (2009), it was found that the Malaysian government had instituted a generic drug policy to ensure continued availability and affordability of essential drugs in community pharmacies for Malaysian citizens. [26]

Conversely, Shrank *et al* (2017) found that patients were less inclined to take generic medications despite acknowledging the cost-effectiveness associated with generic medications. [1] Dunne *et al* (2013) and Haas *et al* (2005) also postulated that both clients/patients and healthcare professionals had a negative perception of generic medication. [27, 28, 1] Whereas, Thomas and Vitry (2009) suggested Malaysian

consumers think that low-priced generic drugs are of lower quality. [26] Similarly, Lambert *et al* (1980) found that 66% of the 510 clients they studied, those clients rejected the cost-effective generic medications. [29]

It should be noted in that 1980-study, 510 clients were evaluated using 18 predisposition variables in reference to generic medications. Their findings showed that two variables particularly influenced a client towards the acceptance of generic medications. Namely, (1) the age of the client because elderly clients were more reluctant to switch to a generic medication alternative/substitute; and (2) perceived notions of cheap drugs are ineffective in treating an illness/disease. [29] Nonetheless, most reviewed literature indicated that the lack of generic drug education/knowledge has had a negative effect on the use and acceptance of generic medications/drugs. Although at the primary healthcare level, one of the most important tools is patient teaching (education) pertaining to medical conditions/diseases and the different treatment strategies that are available; especially regarding the wide range/assortment of pharmaceutical/medicinal products.

In Australia, Hassali *et al* (2005) interviewed 16 clients and found that there were four factors that influenced generic medication usage; specifically, *knowledge/information about generic medications, acceptance of generic medications, non-acceptance of generic medications and educational requirements related to generic medication*. Their findings revealed that most of the interviewed clients were unaware of the term *'generic medications'* but acknowledged the term *'cheaper-brand medications.'* They also found that the reduced price was the major reason for accepting generic medications; in addition, the perceptions and influences of healthcare practitioners also served as a barrier for accepting generic medications. [30]

Hassali *et al* (2005) concluded that clients had a positive attitude towards generic medications but recommended that direct client education provided/offered by healthcare practitioners concerning the efficacy and safety of generic medications can further increase generic medications usage. [30] Likewise in Spain, Valles *et al.* (2003) also conducted a research study to evaluate clients' acceptance of generic medications in management/treatment of chronic-disease conditions in 27 primary healthcare facilities. As part of their research, 4,620 clients received information and educational material pertaining to the advantages and disadvantages of generic medications and original/brand-named medications. Interestingly, 98.9% of those clients agreed to receive generic medications after they were educated on the features of generic medications. Thus, Valles *et al* (2003) concluded that educational intervention in clients results in generic medication acceptance. [31]

The above research findings are further supported by a local study, Stuart *et al* (2017) who assessed patient's perception of generic drugs at health institutions in Trinidad and Tobago. Their research findings revealed that approximately 75% of the participants were unaware of what was a generic drug and 46% of the studied patients labelled generic drugs as *'inferior medication'* and 56% rated the drug as '*fair*.' However, when these said patients were provided with education on generic medications, there was a considerable decrease in the '*fair'* ratings to 20%. They concluded that local patients' perception of generic medications was only enhanced when provided appropriate education on generic medications. [1]

Hence, this' knowledge deficit' among local clients regarding generic medications also provided an impetus and/or justification for this study to comprehensively evaluate clients' satisfaction with generic medications. More importantly, as Stuart *et al* (2017) rightly stated, "*Generic drugs are commonly used in Trinidad and Tobago and it is valuable to the healthcare system; however, it is of little benefit if only a few patients have adequate knowledge about the advantages of generic medications."* [1]

In Canada, Kendall *et al* (1991) studied the various factors associated with generic substitution, satisfaction and intention in purchasing generic medications in a field experiment comprising 295 clients. These Canadian researchers provided these clients with a prescription for a specific condition drug where there was a generic drug and/or an original/brand-named drug suitable in the treatment/management of this condition. The study revealed that more than 80% of the clients when offered the generic drug in substitution for the original/brand-named drug, the clients accepted it. The study also showed that clients who were elderly, less educated and had no health insurance coverage, were likely to accept the generic substitution. [32]

However, there was a low rate of clients' satisfaction with generic medications in those individuals who had financial difficulty, whereas the intention to purchase generic medications was mainly based on previous usage or acceptance of the generic substitute. [32] These findings can be distinguished from Heikkila *et al* (2007) who undertook a research study surveying consumer within a selected community pharmacy. Their findings demonstrated that generic substitution was a successful economic/financial healthcare initiative but if there are poor clients' satisfaction levels with generic substitutes after usage, it is unlikely to be re-purchased in the future. [33] Albeit, Kendall *et al* (1991) study concluded that when clients are provided with various drug options and education on generic medications, clients' satisfaction levels increased which also resulted in the increased acceptance of generic substitution and a strong intention to purchase generic medications. [32]

It seems evident that the above-reviewed literature seems to suggest that typically clients prefer original/brand-named medications rather than generic medications. However, there are many factors that influence the clients' decision in the usage and acceptance of generic medications and/or generic substitutions, for example, lower costs. As the above researchers also indicated, the lack of adequate knowledge/information regarding generic medications has a major role in the decreased use and acceptance of the generic medication as well as clients' satisfaction levels. [32] Therefore, this research study intended to verify the above academic concepts and perspectives and identify if there are additional factors that influence clients' decisions and satisfaction levels. It was also anticipated that the research findings can enhance the medical management of chronic diseases and improve the current shortfalls that exist in the public primary healthcare system by evaluating clients' satisfaction as was done in previous studies.

The Research Study Design and Method of Clients' Satisfaction Evaluation

According to WHO (2000), self-administered questionnaires are generally used to gather data on clients' satisfaction as a convenient and cheap research method. However, research data can also be collected using one-on-one, telephone, or focus groups interview sessions. [22] In the previously-mentioned research studies, it was found that Kendall *et al* (1991) conducted a field experiment using 295 participants (clients) in numerous selected pharmacies; whereas, Heikkila *et al* (2007) utilized a self-administered questionnaire survey within a single pharmacy. [32, 33]

The sample size and research method of the Kendall *et al* (1991) are preferred because it allowed the researchers to make '*fairly'* accurate inferences. [32] According to Leppanen (2016), the target sample population should not be too small because of sampling errors or unusable results. [34] The significant (large) sample size also provided an advantage of providing additional information. For example, to ascertain whether a particular drug had a positive or negative effect on a specific medical condition.

Upon further analysis of Heikkila *et al* (2007) research study, the author opined that there were too many limitations which could affect the accuracy, validity, and reliability of the results. Firstly, a single pharmacy store was used rather than a pharmacy chain that is spread throughout the target population or various pharmacies within the target population. Secondly, the researchers used only two drug variables *(a diuretic for treating hypertension and a sedative for treating insomnia).* One of these medications is not commonly prescribed in chronic disease clients and therefore, the data would have yielded varying, inconsistent acceptance rates and satisfaction scores. Furthermore, the response rate was less than 50% of the targeted sample size which is indicative of a weak research methodology. [33]

Alternatively, Lambert *et al* (1980) utilised a disproportionate sampling method to obtain their sample size. This approach allowed the researchers to provide a larger representation to one or more subgroups to avoid underrepresentation of certain sample strata. The target respondents for this study were elderly citizens, 65 years and older who were sampled from four States in Florida. Then neighbourhoods within each of the four areas were selected based upon their age, income and mobility characteristics. However, the disadvantage of utilising a disproportionate sampling method is that errors can occur in the analysis of the data; thereby, resulting in inaccurate conclusions based on the results of the study. [29]

In the Lambert *et al* (1980) study, the respondents were contacted by professional interviewers who explained the reason for the research study, obtained consent and gave instructions on how to complete the questionnaires. These questionnaires were then sent to the respondents' home and a deadline was given as to when the questionnaires would be collected. [29] It is opined that this research method can be considered a research limitation because some of the respondents may not have fully understood how to complete the questionnaires, especially if the questionnaires were lengthy. Additionally, it was likely given the age variable and sensory impairments might have affected these elderly respondents' ability to complete the questionnaires clearly.

Whilst in the Ganther and Kreling (1996) study, their research design was a cross-sectional survey; a random sample of clients was selected whose ages were 18 years and over. The questionnaires had sixteen items and were mailed to the selected sample. [2] The mailed questionnaires reflected a weakness in the study; principally, the accuracy of the responses to the questionnaires would have been questionable. For example, if the respondents didn't have any medical condition, they may not have used either generic or original brand name medications beforehand, and thus their knowledge in this area would have been an issue. The respondent's age and level of education would have also influenced the results of this 1996-study.

Even though there was no foreknowledge of the respondent's medical condition (if any), the respondents were still asked to give their views on the risk of using generic drugs compared to brand-name drugs in certain conditions. This approach aimed to strengthen the study as it would have removed any bias that a respondent may have had towards the use of either medication/drug. Moreover, if the respondent was in fact already diagnosed with one of the medical conditions, they would have been able to indicate their preference with respect to a certain drug.

Equally, for this research study, the researcher conducted a cross-sectional study guided firstly by the primary research question and then the secondary research questions. The questionnaires were created to satisfy the aims and objectives of the research; additionally, the questionnaires were likened to validated tools used by researchers in the past to evaluate clients' satisfaction. The randomly-selected clients' ages ranged from 18 years and older and the selected chronic diseased conditions targeted were *Diabetes Mellitus (Type 2 DM), Hypertension, Cardiovascular conditions, Cerebrovascular disease, Dyslipidaemia and Asthma.*

The author advanced that there is a similarity between Valles *et al (2003)* study and the proposed research study herein. The 2003-study can be best described as a *"prospective randomized study conducted in one year whereby clients who took chronic-disease medications were provided educational material on generic drugs every time they attended health clinics for repeat prescriptions, in the city of Barcelona."* [31] Hence, the research question(s) were of similar interest and the targeted participants were clients attending primary healthcare facilities for management of their chronic disease conditions. However, the research study was done on a smaller scale given financial constraints, time-frame and physical resource limitations.

Another comparable study was done in Portugal, Figueiras *et al* (2008) in which the researchers adopted a cross-sectional study to survey the level of acceptance in the treatment/management of asthma, common illnesses (influenza) and angina pectoris with generic medications. However, it was found that the respondents had well-established views about generic medications in relation to their efficacy and likeness with original/brand-named medicines. Although the respondents demonstrated a moderate level of acceptance of generic medications for angina pectoris, asthma and influenza, there was a significantly decreased level of acceptance when treating critical medical conditions. [35]

Notably, the participants of this 2008-research study were 18 years and older and were selected from a general population. Thus, these individuals were not clients/patients which was deliberately done by the researchers to strengthen research study by removing any possible or actual bias. Thus, the respondents would not have had one of the above-named chronic disease conditions (asthma or angina pectoris) or had an existing preference between using a generic or original/brand-named medication. However, there was an assumption that the respondent was knowledgeable about the medical conditions being studied. The research variables such as the age of the respondent, level of education and level of income were used to determine if these factors influenced the acceptance of generic medications. Thus, researchers had theorized that those respondents with a high level of education and/or high-income bracket may be more inclined to choose/purchase the original/brand-named drug rather than the generic medication.

In Brazil, Bertoldi *et al* (2005) studied the proportion of generic medication usage from the overall medication used by clients. Additionally, the researchers also analysed the target population's knowledge of the characteristics of generic medications and the contributing factors for purchasing medicines. [36] To undertake this 2005-study, the researchers utilized a questionnaire which included a section assessing the client's knowledge about the generic medications. Consequently, this research study was also able to determine the proportion of generic medications in relation to the total medication used by randomly-selected chronic disease clients.

In assessing knowledge on the characteristics of generic medications, Bertoldi *et al* (2005) developed research questions in relation to:

(a) The costs of both generic drugs and brand name drugs;

(b) The quality of generic drugs and brand-name drugs; and

(c) The distinguishing features of the packaging of generic drugs.

Their research findings revealed that the proportion of generic medications from total medicines usage was 3.9%. Whereas 86% of clients recognised that generic medications cost less and 70% of the clients indicated that the quality aspect of generic medications was like original/brand-named medications. However, the cost of the medications is the main contributing factor that influences clients in purchasing medicines. [36]

Further analysis of Bertoldi *et al* (2005) research design revealed that it was a cross-sectional study in a sample population based in Southern Brazil. Census tracts were used as the primary sample units, whereas the household within each sampled census tract was identified as the secondary sample units. This approach was aimed at strengthening the sampling method utilised and removing the influence of selection bias. The participants who were only 20 years and older were eligible for this study, and those with severe mental impairments were omitted from the study findings/results. Another strong point from this research study was the large sample size used to analyse the results; *n was 3,182*. This large sample size was found to be acceptable to be able to identify any potential correlations between generic medication usage and the independent variables of demographics and socioeconomic status. [36]

Conversely, the Hassali *et al* (2005) research sample size was very small; only 16 clients were studied. As previously stated, a small sample size wouldn't be able to provide accurate, valid or reliable data regarding generic medicine utilization. It is suggested that this research study could have been strengthened by increasing the sample size as seen in Kendall *et al* (1991) and the use of appropriate independent variables, namely age, level of education and level of income, to determine if there was any

association between generic medication utilization as seen in Bertoldi *et al* (2005) study. Although, a quantitative survey was used to obtain data in the Hassali *et al* (2005) study but the sampling technique utilised was a purposive sampling method, which in itself is selective or subjective, it would have thus introduced bias and could have skewed the results obtained.

Regrettably, the above-reviewed literature was predominantly international research studies. Most of the local research studies that analysed clients' satisfaction mainly focused on healthcare professionals and healthcare services/delivery. However, in a recent local study, Stuart *et al* (2017), this research paid particular emphasis on the clients' perception of generic medications. [1] Thus, this research study was follow-up research to further analyse the levels of clients' satisfaction with generic medications. The author also intended to determine if there exists is a relationship with clients' satisfaction with medications and adherence/compliance to prescribed medication.

Therefore, the research design and methodology used in the Stuart *et al* (2017) was adopted by using a comparative cross-sectional study. The targeted sample were clients attending selected chronic-disease clinics at primary healthcare institutions within the NCRHA *(North Central Regional Health Authority).* However, the research sampling procedure differed from the Stuart *et al* (2017) study, who adopted a non-randomised, convenient sampling which had limitations in their research findings. Primarily, their results were unable to be made generalisable to the main population. However, the undertaken research study utilized a randomized sampling process to minimize limitations with expected findings. Whereas the Stuart *et al* (2017) study only evaluated clients' perception, the undertaken research study analysed clients' knowledge and attitude towards using generic medications in the management of their specific chronic disease condition(s). These research findings would be used to provide informative results that can aid in optimising the delivery of healthcare services to primary healthcare clients.

Clients' Satisfaction with Medication and Prescribed Drug Adherence

Although the primary aim and objectives of this research study were to examine clients' satisfaction in relation to acceptance and usage of generic medications, the researcher also aimed to investigate if drug adherence/compliance is linked to clients' satisfaction with generic medications. The justification for this secondary analysis is that poor adherence/compliance with a prescribed drug regimen not only adversely affects the overall health of a client but places a significant and increased burden on the relatives/family, employers, the public healthcare system and the national economy.

According to Dubina *et al* (2009), client satisfaction is a common goal in all aspects of medical management. They further explained that different aspects of a drug regimen such as the number of doses, negligible side effects, dosage form convenience and the lower prices, play a substantial role in client satisfaction. They also iterated that whereas client satisfaction might be the primary goal of medical management, adherence to prescribed medication is critical to the success of that prescribed medical management. [37] Thus, Katusiime *et al* (2016) recommend that given the ubiquitous use of medication in medical treatment/management, client experiences and satisfaction with medications are essential to improving healthcare.

Further review of Katusiime *et al* (2016) study revealed that although medication/drugs are helpful in treating symptoms, avoid worsening of symptoms and sustaining life; regular use of medications for chronic diseases can be challenging. They identified that polypharmacy necessitates long-term medication use which places intensive demands on the client's time, effort, family, employment and finances. These medication challenges can affect client satisfaction and lead to poor drug adherence; ultimately poor treatment outcomes. Additionally, they recognized that other medication factors such as effectiveness, convenience, side effects, medication regimen complexity (frequency and route), physical properties (dosage form) also impact on client satisfaction and drug compliance/adherence. [38]

Notably, Manmohan *et al* (2012) highlighted that terms compliance and adherence are used interchangeably within the healthcare system. However, they made the distinction that compliance is considered '*passive*,' for example, following a doctor's instructions' whereas, adherence demonstrates clients who are '*actively involved'* in their medical management. Nevertheless, both terms were used synonymously throughout their research paper. More importantly, Manmohan *et al* (2012) highlighted that clients who do not fully or partially comply with their medications are the main barriers for effective medical management/treatment. Medication adherence can indeed be quite challenging for healthcare professionals, especially when managing chronic disease clients. These clients require long term follow-up and a barrage of medications to fully optimise their condition. Hence, when medications are not used in the manner it was intended to, such as, improve or maintain the health status, this can lead to frequent hospitalizations, wasted medication purchases, relapse of a medical condition(s) and a huge economic burden on the state. [39]

The above-detrimental consequences can be complicated by the multitude of chronic disease conditions any one client is diagnosed with and as well due to the polypharmacy of medications involved in the management of this one client.

According to Bharmal *et al* (2009), there is a positive correlation with drug adherence and clients' satisfaction; particularly, convenience and effectiveness of the drug. That 2009-study incorporated the use of the TSQM (a validated tool) to evaluate clients' satisfaction using various domains that measured satisfaction factors. [40] Moreover, the findings of Geitona *et al* (2008) does suggest that low client satisfaction may result in poor drug adherence. [41] Thus, monitoring client satisfaction is necessary for evaluating medical treatment/management as it affects clinical outcomes.

However, Geitona *et al* (2008) recommended that client satisfaction with medication should not be limited to measuring clinical outcomes but to evaluate the type of drug and its related drug physical properties. [41] For instance, Brod *et al* (2007) investigated a specific chronic disease, Type 1 DM with the use of pre-prandial inhaled human insulin (PIHI) compared to pre-prandial insulin subcutaneous injections (PISI). Both PIHI and PISI were prepared and used in combination with basal insulin. The focus of their study was to evaluate the relationship between medication (treatment) satisfaction and associated medication variables (insulin-dosage forms). [42]

The researchers found that in a randomized controlled trial study of 299 participants, it showed that there exists an association with medication satisfaction and medication adherence. In that 2007-study, increased medication adherence related to overall satisfaction. [42] Likewise, Testa and Simonson (2007) studied if barriers to insulin drug adherence were linked to medication (treatment) satisfaction. The researchers conducted a comparative analysis of inhaled insulin versus injected insulin and their effects on adherence. This study also demonstrated that increased satisfaction results in reduced barriers drug (insulin) adherence. [43]

Albeit the World Health Organisation (WHO) acknowledged that medication non-adherence/non-compliance remained a major clinical issue for effectively managing chronic-diseased clients within many countries; according to WHO, this noncompliance/non-adherence issue contributed 15% to 93% of public healthcare systems' problems/issues with an average estimated rate of 50%, (Singh *et al* 1996). [44]

Kalogianni (2001) studied the factors that affected patient adherence to medication regimen and classified five inter-related factors that impacted on medication adherence, also termed "*dimensions*" by the WHO:

1. Social/Economic: inaccessible and unaffordable healthcare services, poor social support systems and hectic work schedules are responsible for reduced adherence rates.
2. Provider-Patient/healthcare System: an effective doctor-client/patient relationship has a positive impact on medication adherence. Inadequate education about medications especially regarding their side effects can also contribute to non-adherence.

3. Condition-related: Chronic-diseased clients may be afflicted with more than one chronic disease condition requiring a multitude of pharmacological treatments (polypharmacy), which can be a barrier for medication adherence, especially when clients are asymptomatic.

4. Therapy-related: The polypharmacy of medications utilised in treating chronic-disease conditions and the daily dosing schedules of some of their medications can be a deterrent to medication adherence. The exacerbations of side effects associated with the polypharmacy of medications can as well be associated with reduced adherence.

5. Client-related factors: Elderly, chronic-diseased clients may be experiencing cognitive decline or have physical limitations which can increase the risk for medication non-adherence. Knowledge deficit regarding their chronic disease, together with poor knowledge about the reasons why medications are required as part of their medical management are associated with decreased medication adherence. [45]

It was also found that the dosage of a drug/medication can significantly affect a client's adherence with the prescribed regimen; the *therapy related WHO factor* responsible for medication adherence. Bonnick *et al* (2009) investigated 1,678 clients who were diagnosed and being managed/treated for osteoporosis. Their research was based on evaluating client-satisfaction levels and patient-treatment preferences. Hence, the researchers switched some of the clients from a *'weekly oral bisphosphonate'* to a *'monthly oral bisphosphonate.'* Their research findings revealed that monthly-treated clients were more satisfied than weekly-treated clients, (Bonnick et. al., 2009). They further expounded that the weekly-treated clients had missed some of their dosages and were dissatisfied with their inability to comply/adhere to frequent medication therapy. Therefore, reduce drug/medication dosages enabled drug/medication adherence and increased clients' satisfaction. [46]

However, in a recent research study undertaken by Kim *et al (2018),* posited that medication/drug adherence can have a direct effect on clinical outcomes than the specific management itself. They conducted their research in North Carolina and their findings showed that only 50% of the clients adhered to the prescribed chronic disease medications. Interestingly, these researchers recommended the use of generic medications to improve clinical outcomes and medication adherence because of cost-saving benefits. [47]

Conversely, Auta *et al* (2014) found that 64% of its researched patients were dissatisfied with generic medications, 73% expressed concerned about generic substitution and 21.4% had difficulty adhering to drug therapy. [48] Likewise, Hakonsen *et al* (2009) reported that one-third of their patients had a struggle with generic substitution and adhering to their prescribed medications. [49] Despite the aforementioned-research findings, Van Wiijk *et al* (2006) concluded that generic substitution does not affect medication/drug adherence. [50]

Therefore, the above-reviewed literature illustrated that there is an apparent relationship with clients' satisfaction with medications and medication adherence. Moreover, it cannot be underscored that this research subject/topic has been limited by published research and academic literature to support the relationship between clients' satisfaction and medication adherence, particularly the barriers to medication adherence. Whereas, the author of this research study herein aimed to substantiate the above-reviewed literature and academic perspectives.

RESEARCH METHODOLOGY

The research methodology explained the type of research method that was adopted to collect pertinent research data (both secondary and primary data). Ghauri and Gronhaug (2005) defined research as an organized activity that the researcher engages in to learn and increase their knowledge.[51] The following paragraphs would describe and explain the various components of how this research study was undertaken.

This research study was a cross-sectional survey that aimed to evaluate clients' satisfaction towards the use of generic medications in the management/treatment of specific chronic-disease conditions. This evaluative study was a follow up to an initial research study that evaluated clients' perception of generic medications in Trinidad and Tobago's public healthcare system. However, that study was done within a pharmacological discipline; whereas this was a comprehensive study to evaluate clients' satisfaction with generic medications use in chronic diseases, and secondarily, drug adherence to generic medications.

Healthcare Services Delivery

The Republic of Trinidad and Tobago is a twin-island state within the Caribbean Commonwealth. Trinidad and Tobago's healthcare system is demarcated into private and public healthcare services to treat both acute and chronic medical conditions/diseases. Nonetheless, both private and public healthcare systems are governed by the Ministry of Health of Trinidad and Tobago for safe, professional and quality healthcare delivery to the citizenry of Trinidad and Tobago. [52]

However, the undertaken research study was limited only to Trinidad with a concentration on the public healthcare system. Trinidad was chosen because it is physically larger of the two islands and densely populated. Furthermore, the public healthcare system was preferred because there are healthcare departments/units that specifically manage/treat chronic-disease clients/patients.

Unlike the private healthcare systems, the public healthcare facilities are decentralized and managed by Regional Health Authorities (RHAs) which are similar to the National Healthcare System (NHS) in the United Kingdom. All of the RHAs are regulated by the Regional Health Authorities Act No. 5 of 1994 in the provision of primary, secondary and tertiary healthcare services within Trinidad and Tobago.[52]

Each RHAs are considered governmental/state administrative agencies that manage diverse regions based upon their geographical locations, for example, North West, North Central, Eastern and South West of Trinidad with varying geographic location (physical) and demographics. For the purpose of this research

study, the North Central region was chosen by the researcher based on her familiarity and professional work experience within the NCRHA. The public healthcare services offered by the RHAs are generally free and available throughout Trinidad and Tobago which is subsidized by the government, more particularly, tax payments and health surcharge subventions. [52]

Within the chosen healthcare region (NCHRA), there is a further administrative subdivision of the health facilities into clusters or managing groups which report to the executive management of the NCRHA; namely, Chaguanas, St. Joseph and Arima clusters. Hence, the researcher selected primary healthcare centres within the Arima cluster. These primary healthcare institutions were recognised as an appropriate sample population for chronic-disease clients. There are seven (7) health centres in the Arima cluster, namely, Arima, Maloney, La Horquetta, San Rafael, Talparo, Brasso Seco and Blanchisseuse health centres.

However, only San Rafael, La Horquetta, and Arima Health Centres were selected to provide a diverse sample population based on the socioeconomic, ethnic, religious and educational background. Moreover, these selected health centres suitably represented and/or reflected the "overall" primary healthcare facilities and services offered in the region. Hence, these three health centres provided primary healthcare services for walk-in clients in the management of children/baby health, maternal health, adult health, family-planning, wellness and chronic diseases for individuals within that particular region.

Participants of the Research Study

As previously mentioned, the chronic-diseased clients were selected because these individuals were commonly prescribed multiple medications for medical treatment/management of their medical conditions compared to other healthcare patients. Thus, an 'inclusion criteria tool' and 'exclusion criteria tool' were used to select the research participants to ensure reliability and validity of the research study. It must be emphasized that a random selection process was utilized to allow chronic-diseased clients to participate in the research study using both the inclusion criteria tool and exclusion criteria tool.

I. Inclusion Criteria:

- Chronic disease clinics at San Rafael Health Centre, La Horquetta Health Centre and Arima Health Centre of NCRHA, Trinidad and Tobago.

- Adult chronic-disease clients (18 years of age and older) who attended the above three chronic disease clinics.

- Adult chronic-diseased clients who were managed for the specific chronic disease conditions: *Diabetes Mellitus (Type 2), Hypertension, Cerebrovascular Disease, Cardiovascular Disease, Dyslipidaemia and Asthma.*

II. Exclusion Criteria:

- Clients who had an underlying psychiatric and/or psychological disorder in addition to the above-specified chronic disease conditions.

- Clients who were too unstable/unwell at the time of the research study.

RESEARCH SAMPLING

The research sample size was calculated using the following formula:

$$n = \frac{z^2 P (1-P)}{d^2}$$

with Z = 1.96 (assuming a 95% Confidence Level)

d = 0.05 (precision)

P = 50% (0.05).

This research study aimed to evaluate the proportion of target clients who were satisfied with the use of generic medications in the management of selected chronic-disease conditions; the value of which was unknown.

Notably, the number of clients who were adherent or non-adherent with their medications for the management of their chronic-disease conditions also remained unknown, as both of these particular areas remain un-researched and/or un-investigated. Therefore, the standard of using 50% when the proportion was unknown is as follows:

$$\text{Thus } n = \frac{1.96^2 (0.5) (1- 0.5)}{0.05^2}$$

= 384.16 which is equivalent to 384

The research study also took into account a 20% non-response rate; the adjusted sample size worked out to be:

(20% x 384) + 384 = 77 + 384

= 461 participants

The sample size was rounded off to 470 participants.

Research Sampling Process

As previously mentioned, the selected health centres (3) from the Arima cluster under the management and administration of the NCRHA (North Central Regional Health Authority) were examined for this research study, namely the San Rafael Health Centre, La Horquetta Health Centre and Arima Health Centre. The following paragraphs provided justification for their selection.

The Arima Health Centre was selected because of its extensive geographical region which provided approximately half of the sample size within this particular chronic disease clinic. The ideal sample size from the Arima chronic-disease clinic for this research study was two hundred and thirty-six participants (236).

Whereas the remaining sample size was evenly distributed between the other two health centres: specifically, La Horquetta Health Centre (ideal sample size of 117 participants) and San Rafael Health Centre (ideal sample size of 117 participants). It was found that the geographical region of both areas was similar, and as well, the composition of clients who attended both the chronic-disease clinics had similar attendance. Hence, it was in the professional opinion of the author that these two chosen health centres satisfied the aims and objectives of this research study.

The research sampling process involved reviewing the 'Chronic Disease Register' located at each of the studied health centres. The Chronic Disease Register (CDR) was a book that provided the names of all the chronic-disease clients with their pertinent demographic information such as age and gender, their applicable chronic disease condition/illness, and their clinic attendance. The CDR was the sample frame for this research study. The researcher randomly selected names from the CDR books at each of the three selected health centres using random number table.

For San Rafael Health Centre, the researcher randomly selected 180 participants which represented approximately 60% of the chronic-disease sample population. Following this, the inclusion and exclusion criteria tool was applied to this sample of potential clients and of this sample, 117 clients were administered the survey. This was done to ensure that the appropriate proportion of the sample population was achieved, thereby ensuring that the results were reliable and valid. The rationale for randomly sampling an increased number of participants was to account for those clients who declined and/or who were unable to participate in the research study. Therefore, this increased selection ensured that the appropriate proportion of the sample population was achieved, thereby ensuring that the results were reliable and valid.

The similar selection process was repeated in the La Horquetta Health Centre by randomly selecting the same target population. However, for the Arima Health Centre, because of the larger geographical region, 300 participants were randomly selected which represented 60% of the chronic-disease clients; of this population, 236 clients were administered the survey.

Each research participant who gave written, informed consent, and participated in the survey were assigned a research number for this research. However, if a chosen participant was unwilling to partake in the survey, then another random participant was selected from the sampled population. This was done to ensure that the adequate sample size was achieved.

Additionally, these health centres were selected to ensure homogeneous characteristics amongst the study participants. It was also intended to limit potential confounding variables such as age, the highest level of education and level of income, as variables could have impacted on the validity and reliability of the research study findings. More importantly, as per the reviewed literature, a large random sample ensured that the aims and objectives of a research study were attained.

RESEARCH STUDY DESIGN

This research study was a descriptive/observational and/or cross-sectional study. A cross-sectional study is defined as, *"a research study that analyses data from a target population or a representative subset of the population at a specific point in time,"* (Mann, 2003). [53] The primary research data was obtained from randomly-selected clients assessing their knowledge about the use of generic medications in the treatment/management of their chronic-disease conditions.

There are several advantages to performing a cross-sectional study because it can be used to prove and/or disprove assumptions *(generic medications are inferior)*. It was found by previous researchers that cross-sectional studies are not costly and time-consuming to perform. Thus, a cross-sectional study allows the researcher to capture a specific point in time and multiple variables can be analysed at a specific time period.

As discussed in the above-reviewed literature, a 2005 cross-sectional study was conducted in Southern Brazil to evaluate the knowledge and use of generic drugs/medications in adult clients. The cross-sectional study utilized a sampled population in a Southern-Brazilian city to analyse the following:

- *the proportion of generic drugs of the client's total medication.*
- *the extent of theoretical and practical knowledge the clients had regarding generic medications and*
- *the diverse strategies utilized by clients to purchase prescribed medicines.*

Therefore, based on that 2005-Brazilian study, the cross-sectional study design was considered suitable to collect data as it was analogous to research study undertaken in Southern Brazil. [36] The 2005-Brazilian study utilised census tracts defined by the *Instituto Brasileiro de Geografia e Estatistica* (IBGE) as the primary source of research data, likewise, the CDR was utilized in this research study.

However, (Mann, 2003) postulated that cross-sectional studies do have their disadvantages such as they cannot be used to analyse human behaviour over a period. He goes further to explain that cross-sectional studies cannot ascertain the cause-and-effect relationship, and the timing is not guaranteed to be truly representative. [53] There may be challenges in putting together the sampling pool based on the number of variables of the population being studied.

Nonetheless, the author/researcher did initially consider case-control studies for this undertaken research study design. Cross-sectional studies are generally different from case-control studies because cross-

sectional studies entailed researching and obtaining data on the entire target population, whereas case-control studies usually research participants with a specific characteristic, often a small minority population. In addition, case-control study findings would have already been established and the outcome would have already occurred; with regards to that aspect, participants were already diagnosed with at least one of the specified chronic-disease conditions for this cross-sectional study.

However, a case-control study would be more suitable for rare diseases rather than common diseases. Despite the advantages of performing a case-control study, such as, its cost-effectiveness, shorter duration and usefulness when exposure data is hard to obtain, the disadvantage is that a case-control study involves selection bias which can negatively impact on the objectivity, validity and reliability of analytic data and the corresponding findings/results obtained. Similarly, information on exposure is subjected to observation bias.

Moreover, the author/researcher found that it may have been difficult to assess satisfaction levels in the use of generic medications in chronic-disease patients because of the complexity of each participant's disease process, medication knowledge and individual health status (risk factors) which differs in varying degrees for each individual. According to Mann (2003), a case-control study is more suitable for researching medical diseases/illness in two groups of patients rather than analysing customer satisfaction levels. [53]

Finally, the author/researcher also deliberated on using cohort studies as these can be performed either retrospectively or prospectively. Mann (2003) stated that prospective cohort studies are inefficient unlike retrospective cohort studies which are efficient because it takes less time to assemble the participants and large amounts of research data can be collected. Retrospective cohort studies provide a lack of bias because the outcome of interest was not the original reason for the research study. [53]

However, based on the aims and objectives of this research study, it was difficult to determine client's satisfaction without the use of a validated questionnaire. Mann (2003) postulated that retrospective cohort studies are much cheaper as the data have already been collected. The outcome would have already occurred. [53] Although clients' medical records can be analysed for a retrospective cohort study, it may not have been a true reflection of the client's satisfaction with the use of generic medications.

RESEARCH STUDY APPROACH

For this research study, data was obtained/collected using interviewer-administered questionnaires. The questionnaire structure incorporated a Knowledge and Attitude survey element(s) and was administered by an interviewer (a healthcare professional). This cross-sectional study utilized the Knowledge and Attitude parts of the survey as an appropriate method of collecting both quantitative and qualitative data. Thus, randomly-chosen clients were interviewed using the Knowledge and Attitude formulated questionnaire to seek an understanding of their knowledge about generic medicines (qualitative research data). The other section (Attitudes) of the questionnaire provided quantitative research data.

Research data regarding clients' satisfaction was collected with the use of questionnaires which incorporated the validated *Treatment Satisfaction Questionnaire for Medications (TSQM- Version 1)* that utilized a Likert scale. [54] Based on reviewed literature, thus far, there are two generic questionnaires which are quite suitable for researching chronic disease conditions: the *Treatment Satisfaction Questionnaire for Medications (TSQM- Version 1 or 11)* and the *Treatment Satisfaction with Medicines Questionnaire (SatMed-Q).* [55,56]

The SatMed-Q has matching domains as the TSQM- Version 1 or 11, but additionally, there are two additional domains: specifically, *the impact of the treatment on daily life* and *quality of monitoring by health professionals*. Thus, the added domains of the SatMed-Q may offer an advantage compared to the TSQM- Version 1 or 11. Each domain was verified for the reliability of both questionnaires and revealed the Cronbach's coefficients were reported to be around 0.9 for each domain item. Predominantly, the domains of *side effects, effectiveness, the convenience of use, impact on daily activities* and: thereby suggesting excellent internal consistency. [55, 56]

Nevertheless, TSQM-Version 1 was chosen as the validated tool to assess the clients' satisfaction with generic medications.

In addition, the *Medication Adherence Questionnaire* (validated tool) was used to collect data regarding clients' adherence with generic medications. The Medication Adherence questionnaire consisted of twelve (12) questions with binary answering choices: *yes or no* and has a scoring algorithm as well. According to this validated tool, clients are considered to be at risk for nonadherence when the total point scored is 2 or higher. [57]

This adherence scale also illustrated the potential reasons/factors (research data) of non-adherence based upon the answers provided by the respondents; namely, *the clients' health literacy, potential memory impairment, clients' health beliefs, potential physical/functional disability and socio-economic concerns*. [58]

According to the adherence scale, this research study was able to obtain relevant research data on adherence or contributing reasons/factors from the following questions of the questionnaire:

- Questions: 1 and 7 of the Medication Adherence Questionnaire provided information on a clients' health literacy. ***(Appendix F, Fig 16.1 and 16.2).***

- Questions: 2, 9, 10 and 11 showed potential memory/ forgetfulness problems. ***(Appendix F, Fig 17.1, 17.2, 17.3 and 17.4).***

- Questions: 3, 4 and 8 showed client's health beliefs. ***(Appendix F, Fig 18.1, 18.2 and 18.3).***

- Question 5 provided information on potential physical and/or functional disability. ***(Appendix F, Fig 19).***

- Question 12 indicated financial concerns. ***(Appendix F, Fig 20).***

Objectively, the author/research acknowledged that there are different methods for evaluating and/or measuring medication adherence; however, though there is no gold standard approach and/or benchmark research tool. One of the widely-used questionnaires to assess medication adherence is the Morisky Medication Adherence Scale, which was the initial tool that was considered for this research study. Unfortunately, this chosen research tool was not available without gaining permission from the authors and when this was sought, the researcher/author did not obtain the authorization to use this research tool. Therefore, it would have been unethical and illegal to proceed with this research study using the Morisky Medication Adherence Scale; hence, author/researcher recognized this as a limitation in this research study.

Nonetheless, the author/research was able to utilize the *Medication Adherence Questionnaire* because it is another reliable and valid tool to measure adherence to medication. [59]. It was designed to screen for general medication adherence versus disease-specific medication adherence which is what the Morisky Medication Adherence Scale was designed to measure adherence in hypertensive and asthmatic clients. This research tool was found to have a moderate to high test/retest reliability with a correlation coefficient of 0.699 and a moderate internal consistency with Cronbach coefficient of 0.584. [59]

More importantly, the benefits of using a questionnaire which provides both quantitative and qualitative research data would be valuable in comprehensively evaluating clients' satisfaction with generic medications. Hence, the use of this secondary research tool achieved the aims and objectives of this research study which were to evaluate and discuss the reasons for clients' non-acceptance and/or usage of generic medications in the target population.

Simply put, to assess the clients' knowledge and attitudes regarding generic medications and to highlight the factors that influence their satisfaction of generic medications. ***(Appendix F- Tables 8 and 9- linear regression)*** Moreover, the collected quantitative data also allowed the researcher to evaluate the clients' medication-use history with an emphasis on drug adherence. Moreover, the research findings (data) were further analysed with the use of SPSS software to ascertain clients' satisfaction ratings and other appropriate statistical information.

DATA COLLECTION

The collection of research data was greatly dependent on the ethical approval granted by the *Research Ethics Committee of the Faculty of Medical Sciences, University of the West Indies, St. Augustine*, as well as authorization from the Chief Executive Officer (CEO) of NCRHA (North Central Regional Health Authority) for the study to be conducted at the selective health centres. Ethical approval was necessary since the study involved human participants and their medical data. Thus, the Research Ethics Committee only granted approval as the study did not infringe the safety, dignity and rights of the clients. This research study took all of those elements into consideration and there was no misconduct on the part of the researcher. Approval was obtained from the *Research Ethics Committee of the University of the West Indies* on the 27th September 2019. ***(Appendix A)***

Administrative permission was granted from the CEO of NCRHA to access clients' medical records and for the use of the primary healthcare facilities for the study to be conducted in the Arima Cluster. Therefore, the researcher was able to access each Chronic Disease Register at the selected health centres for random sampling to occur. The CEO was assured that the confidentiality and security of all medical records were always maintained, and that the researcher cooperated with the medical records department staff thereby ensuring no disruption to healthcare services. Verbal approval was granted from the CEO on the 18th October 2019; official letter received on the 21st October 2019. ***(Appendix A)***

The randomly-selected participants were provided information outlining the nature and purpose of the study. They were informed that all relevant authorizations were obtained thereby demonstrating that the research study was legitimate and ethical. More importantly, it was explained to the participants that they had the option to refuse participation in the research study. Data was collected once informed and written consent was obtained. During the research (one-on-one interview) process, participants were reminded and reassured that confidentiality was always maintained during and even following completion of the research study. ***(Appendix A and B)***

Six hundred and sixty (660) potential clients were randomly selected from the Chronic Disease Register Books at the designated health centres: *three hundred (300) from Arima Health Centre, one hundred and eighty (180) from San Rafael Health Centre and one hundred and eighty (180) from La Horquetta Health Centre*. The inclusion/exclusion criteria tool was then applied, after reviewing the clients' medical records. Of the 660 potential clients, five (5) clients were excluded from the study due to their other diagnosed medical conditions which satisfied the exclusion criteria tool. The remainder of the randomly selected clients were then contacted via telephone and the research study was explained to each of the

contacted individuals. ***(Appendix C)*** Permission was sought from each client to partake in the study. Once verbal consent was obtained from each of the clients, arrangements were then made for the participants to visit their designated health centres where the questionnaires were administered by an interviewer in a private and professional manner. Data was collected from 470 (71.2 %) participants in total: *236 participants from Arima Health Centre, 117 participants from La Horquetta Health Centre and 117 participants from San Rafael Health Centre.* Twenty (20) clients declined to participate in the survey following the verbal conversation; seventeen (17) clients were unreachable via their telephone contacts and eighty-eight (88) clients were not contacted as the sample size of 470 was attained.

To ensure valid and reliable results, the medical records of each participant were examined to identify their current polypharmacy. Also, as part of the verification process, the participants walked with their medications on the day of their interview. Confidentiality and professionalism were always maintained.

The researcher recruited several interviewers (research assistants) who were trained and qualified healthcare professionals. The interviewers underwent training prior to the commencement of the research study and a research protocol was developed for the purpose of data collection, thereby ensuring that the data collection method was reliable and valid. ***(Appendix D)***

Data Collection Tool (Validated)

As previously mentioned, the interviewer-administered questionnaire incorporated the *TSQM-Version 1,* the *Medication Adherence Questionnaire,* and the following Knowledge and Attitude question elements:

- Section A of the questionnaire collected socio-demographic data from each participant. Data on *age, gender, marital status, the highest level of educational level and monthly income* were collected. In this section as well, each participant was asked to indicate which chronic disease condition(s) they were being treated for in the chronic disease clinic. Participants as well were asked to specify how long they had been diagnosed with their chronic disease condition(s) and how long they had been receiving treatment for their specific chronic disease condition(s).

- Section B had questions asking participants knowledge of generic medications. This was in the form of a Likert scale that provided a range from *Strongly Agree to Strongly Disagree,* and the participant had to choose the most appropriate answer for each of the questions asked. The last question in this section asked clients to identify if they had switched from using generic drug/s to original drug/s for the management of their chronic disease condition(s), and they were asked to state their reasons depending upon their response. This was to determine the proportion of clients who were using generic medications for their chronic disease management.

- Section C had questions centred on participants' attitude towards generic medications. This as well took the form of a Likert scale with the participant choosing the most appropriate response.

- Section D involved the application of the *Treatment Satisfaction Questionnaire for Medication (TSQM-Version1).* Although the original TSQM questionnaire consisted of 55 questions, only 14-question items were selected but remained a validated instrument. These 14 questions were considered suitable because they were psychometrically robust and assessed the following domains of clients' satisfaction: *symptom relief/efficacy, side effects, ease and convenience, impact on health-related quality of life and general satisfaction.* This component of the interviewer-administered questionnaire has a scoring algorithm which ranged from 0 to 100; therefore, no computed score was lower or higher than these limits. ***(Appendix E)***

  - The domain of effectiveness as it relates to clients' satisfaction in the TSQM was created using the scoring algorithm and the first 3 questions in this questionnaire. ***(Appendix E)***

  - Likewise, the domain of convenience as it relates to clients' satisfaction in the TSQM was created using the scoring algorithm and questions 9 to 11 in the questionnaire. ***(Appendix E)***

  - The domain of side effects was created using the scoring algorithm and questions 5 to 8 in the questionnaire. ***(Appendix E)***

  - The variable of overall satisfaction in the TSQM was created again using the scoring algorithm and questions 12 to 14 in the questionnaire. ***(Appendix E)***

- Section E involved the application of the *Medication Adherence Questionnaire* which was another validated tool. The participants' responses were limited to varying response options based on the question. The questionnaire consisted of 12 questions with binary answering choices: Yes or No. The questions each looked to ask questions pertaining to adherence; with the scoring algorithm which assessed a higher risk for clients being non-adherent when the total point scored was 2 or higher. ***(Appendix E)***

DATA ANALYSIS PLAN

For the purposes of this research study, the author designed a questionnaire that was adapted to incorporate reliable and validated research tools to undertake the data-collection process. Thereafter, the information received was entered, coded, and analysed utilizing Statistical Package for the Social Sciences version 21 (SPSS). The author/researcher analysed the data in various categories, mainly, frequencies, scoring algorithms, and regression techniques to illustrate the research findings in a clear and concise manner.

The frequencies of the demographic characteristics, knowledge and attitudes of participants were calculated in order to obtain a profile of the sample to help identify the source of the responses given and to provide additional background as to the needs of the participants and provide further context to decisions they made. Whereas the scoring algorithms for new variables non-adherence, effectiveness, side effects, convenience and overall satisfaction by participants as it related to generic medications were calculated in SPSS.

It should be noted that additional analysis was undertaken during this research to assess overall the risk of a client being non-adherent with their medication(s), based upon the scoring algorithm from the Medication Adherence Questionnaire. Moreover, logistic regression and linear regression were used to determine the impact associated variables had on risk of non-adherence and overall clients' satisfaction with generic medications.

Initially chi-square and t-test analyses were performed to identify correlations among the variables and the information collected in the study instrument including the newly calculated variables effectiveness, side effects and convenience; then a logistic regression was used to determine the variables that impacted participant's non-adherence as the non- adherence variable is binominal in nature and as a result met the criteria for logistic regression. The author/researcher utilized linear regression to ascertain the impact variables had on participant's (client's) overall satisfaction which was a continuous variable.

Upon completion of the data analysis, the research results and/or findings were interpreted and represented in the form of tables and graphs and discussions where appropriate.

PILOT STUDY

The interviewer-administered questionnaire was considered suitable for this study because it minimized and/or eliminated errors and misunderstandings. A pilot study was conducted to determine the feasibility of the research, the practicality of data collection and analysis, the appropriate selection of interviewers (research assistants) and identify unforeseen research-related problems/issues. Moreover, it provided the foundation for the research study.

The pilot study allowed for the researcher to have effective and efficient time management when it came to conduct the research study. Therefore, the researcher was able to ascertain the average time it took to complete an interviewer-administered questionnaire. Appropriate revisions/corrections were made thereby ensuring that the research had no delays or overruns in data collection. Additionally, the researcher was able to analyse the level of difficulty the questions posed to the pilot participants and thereby ensured that they were able to comprehend and respond appropriately.

The pilot study was conducted at La Horquetta Health Centre and consisted of 20 chronic disease clients who satisfied the inclusion criteria. Informed and written consent were obtained from the pilot test participants; discrepancies or misconceptions that the pilot participants had were also addressed. The researcher also observed potential interviewers (research assistants) thereby ensuring that they displayed appropriate professionalism and competence in performing the interview. The pilot study was carried out on the 22nd October 2019.

At the end of the pilot study exercise, feedback was gathered from both the participants and interviewers. Their critiques, suggestions, concerns and/or general comments were taken into consideration and the questionnaire was modified appropriately. The same applicability of strict confidentiality was maintained for the pilot study.

RESEARCH BIAS

Bias refers to a systematic error in a research study whereby an element during the research influenced the outcome/results. There are various ways in which biases can occur in research, chiefly, poor study design. Thus, during the research study, appropriate measures were developed, implemented, and evaluated at each phase to prevent biases from occurring. Research bias should be treated with significant importance because even a subtle bias can negatively affect the reliability and validity of the research findings.

Firstly, to prevent bias in this study, the method of sampling participants from the selected health centres was done randomly. This meant that each participant had an equal chance of being selected for the research study, thereby removing the possibility of *selection bias*.

Secondly, the content and structure of the interviewer-administered questionnaires were the same which also eliminated bias.

Furthermore, a pilot study was undertaken to identify and address any actual and/or potential problems, issues, concerns or discrepancies that may have materialized in the study. All relevant and suitable revisions to the interviewer-administered questionnaires were made before commencing the study with no further changes. This measure ensured internal validity.

Thirdly, as mentioned earlier, primary research data was collected using interviewer-administered questionnaires. It was a requisite for both the pilot study and the formal research study that the interviewers were trained and qualified healthcare professionals. More importantly, they were appropriately trained to not only minimize data collection errors but also to prevent the interviewers from influencing the participants' responses. Hence, a protocol for data collection was developed and it was rigidly followed to minimize and/or prevent *interviewer/observer bias*. (**Appendix D**)

Unfortunately, *recall bias* was another type of bias that occurred within the research study, for instance, in section E of the interviewer-administered questionnaire which sought to assessed drug adherence. Some of section E questions required the participants to state which medications they had forgotten to take within the past week, their frequency of missing these medications and the reasons for not taking the medications. Some of the participants were unable to accurately recall and respond accordingly. Thus, this could have resulted in some aspect of recall bias which was somewhat difficult to avert.

Finally, another potential bias that was taken into consideration for this research study was *response bias*, also known as the *'Hawthorne effect.'* With this type of bias, the respondents were aware that they were being observed, especially, in an interviewer-administered questionnaire. Consequently, the respondents may have answered the questions in a manner that they thought the research study wanted them to answer, not an accurate reflection of their actual thoughts. However, this type of bias was thereby minimized by asking participants to answer honestly prior to commencing the interview (data-collection).

ETHICAL CONSIDERATIONS

Generally, a researcher must consider the various ethical considerations that must be practiced and maintained when undertaking a research study. Hence, the researcher for this research study obtained approval from the Research Ethics Committee of the Faculty of Medical Sciences, University of the West Indies, St. Augustine, the CEO of NCRHA, and other relevant academic and/or healthcare authority.

Once the appropriate approval was granted by the above-mentioned professional body(ies) and authority(ies), the research data was only collected once voluntary and informed consent were obtained from all of the randomly-selected participants. The researcher ensured that the consent of these individuals (participants) was obtained without coercion and that the purpose of the research study was fully explained to them. A participant who was assessed to not have the mental capacity to provide informed consent to the study, was excluded from participating in the research study, for example, the five clients who had known psychiatric disorders. Therefore, both the researcher and research assistants remained diligent and observant thereby ensuring the validity and reliability of the research findings.

More importantly, the researcher did not engage in any behaviours or acts that may have appeared to be an inducement (bribe) or tangible benefit (gifts) for the participants to partake in the research study. Each participant was provided with the relevant details such as the aims and objectives of the research study, what the data collection process entailed and the benefits of the study; this eliminated the need to influence or coerce participants. This notion is supported by the World Medical Association Declaration of Helsinki (2009) who stated that any medical research involving human subjects, everyone (human) should be sufficiently informed of the aims and methods of the study. The latter association further expounded that all aspects of the research, such as but not limited to, *the sources of funding (self-funded or sponsored), potential conflicts of interests, the expected benefits, and possible risks or discomforts the research entails* should be told to the participant. [60]

Furthermore, participants were informed of their right to 'refuse to participate' in the research study, and their right to withdraw 'consent to participate' at any time without reprisal or negative consequences. Notably, the researcher was a medical practitioner. Any participant that declined to participate in the research study, their decision did not negatively impact on the client-doctor relationship. The researcher maintained her professionalism and extended all due courtesies to all randomly selected participants before, during and after the research study. It was incumbent that as a licensed medical practitioner that the researcher maintained professional and ethical conduct whilst providing medical care to actual and/or potential clients.

The researcher sought assistance during this research study. More particularly, assistance regarding the interviewer-administered questionnaires. Thus, the potential interviewers were also qualified healthcare professionals who were competent to administer the questionnaires in accordance with the highest research ethical standards and principles. Additionally, appropriate training was provided, and a research protocol was developed which ensured an unencumbered data collection. Training of the research assistants and the development of the research protocol was done during the period 23rd October 2019 to the 25th October 2019.

By choosing healthcare professionals as research assistants for the administration of the questionnaires, confidentiality was always maintained (during and even after completion of the study). Maintaining confidentiality is a critical role for every healthcare professional and therefore, protecting a client's medical history or their privacy did not pose any challenges in this regard.

Additionally, research participants were not referred to by their legal names or any references that may have revealed their identity. However, the consent forms had their names to ensure the legality of informed and written consent. Additional caution was taken to store both the signed consent forms and completed questionnaires in a locked fire-proof filing cabinet. Absolutely no research data was divulged to anyone outside of the research team.

The environment to conduct the interviewer-administered questionnaires was one that provided adequate privacy for data collection. The World Medical Association Declaration of Helsinki (2009) further stated, *"It is the responsibility of medical doctors who are involved in medical research to promote and protect the health, well-being, and rights of the patients."* They emphasized that the researcher should ensure that whilst undertaking research, any possible harm to the participant should be minimized.[60]

Participants were advised of the opportunity of being informed of the research study outcome/findings if they so desired. They were also informed and assured that confidentiality and privacy would be maintained if the research findings are published. Any disclosure of a patient's medical information without further consent would have legal ramifications for the researcher. Nonetheless, the researcher was prepared to be held fully accountable for the completeness and accuracy of the research report. To ensure validity and reliability, any negative, inconclusive results, as well as positive results would be published. Hence, the data collection procedure and data analysis were done with honesty and integrity.

The researcher maintained strict financial propriety and accountability. The researcher remained diligent to identify potential and/or actual conflict of interests and took the necessary steps to maintain transparency, objectivity and to avoid partiality and/or research bias. These aforesaid research principles for the research study were in keeping with well-established ethical research standards.

Notwithstanding all of the above, the researcher did not proceed until the Research Ethics Committee of the University of the West Indies, St. Augustine, was contacted and approval was obtained, as the researcher was mindful that any data collected before the said approval was granted couldn't be used for analysis or as research findings.

RESEARCH LIMITATIONS

Generally, research studies have limitations, and this is considered normal in the execution of research process. However, it was necessary to identify and/or highlight the associated limitations with the research study that may have impacted the research findings/results. By not making mention of the limitations, diminishes the validity of the research. Therefore, the principal researcher recognized the following limitations as conditions/situations, circumstances, short-comings, or influences that could not have been controlled.

Firstly, as previously aforementioned, the proposed research tool (Morisky Medication Adherence Scale) that the researcher had intended to use to evaluate and/or measure medication adherence, the permission/authorization was not granted from the authors/creators of this said tool. To ensure that this research study adhere to research ethical principles, the researcher substituted with another reliable and validated tool to achieve the research aims and objectives.

Specifically, the scoring algorithm for the Medication Adherence Questionnaire provided the information for identifying clients who were at a higher risk for medication non-adherence. It would be have been useful to utilise an appropriate adherence tool for determining the proportion of clients who are actually adherent with their medications, even though when measuring medication adherence one still needs to consider an aspect of medication non-adherence or specifically the barriers to medication adherence.

Secondly, within the demographic data section, in the marital status and monthly income questions, the research assistants inadvertently failed to provide appropriate responses for a few of the randomly chosen interviewed participants. As well, the data obtained for the highest level of education and the monthly income was skewed more towards the left.

Thirdly, there existed a poor medical record management within the healthcare system. The CDR books were not appropriately updated and as such did not reflect the accurate number of primary healthcare clients in the book, their present medical state and as well their contact information. There was also a separate book for the sole registering of only diabetic clients; whereas the CDR books contained clients who had other chronic medical conditions, in addition to being a diabetic.

Finally, the research study did not have a large target sample population as seen in the reviewed literature. The target sample population was considered suitable to the principal researcher because of time and financial limitations in conducting this cross-sectional study. Ethical approval from all the relevant

authorities took a substantial time before the actual study was undertaken, thereby placing a time constraint on data collection. However, given the reduced time frame which was not anticipated in the initial planning stage for this study, data collection was completed.

PRESENTATION OF RESULTS

- INTRODUCTION

As a quantitative, descriptive study, the research instrument was designed to calculate the responds by participants and was used to gain an understanding of the makeup of the sample, their knowledge, attitudes, overall satisfaction, and increased risk of non-adherence with the generic medications they were taking. This chapter explored the findings from the data collected via the research instrument. Descriptive statistics and frequencies were utilized to obtain the respondent's demographic characteristics, attitudes, knowledge and increased risk of non-adherence. The TSQM algorithm was used to calculate the overall satisfaction, convenience and effectiveness of respondents towards generic medications. A bivariate analysis was used to determine associations among the demographic variables and the overall satisfaction and the risk of non-adherence towards clients. Finally, linear and logistic regression analyses were carried out to address the research questions in determining the factors that had an influence on overall satisfaction and the risk of non-adherence respectively.

Demographic Profile

Figure 1 Gender Composition of Respondents

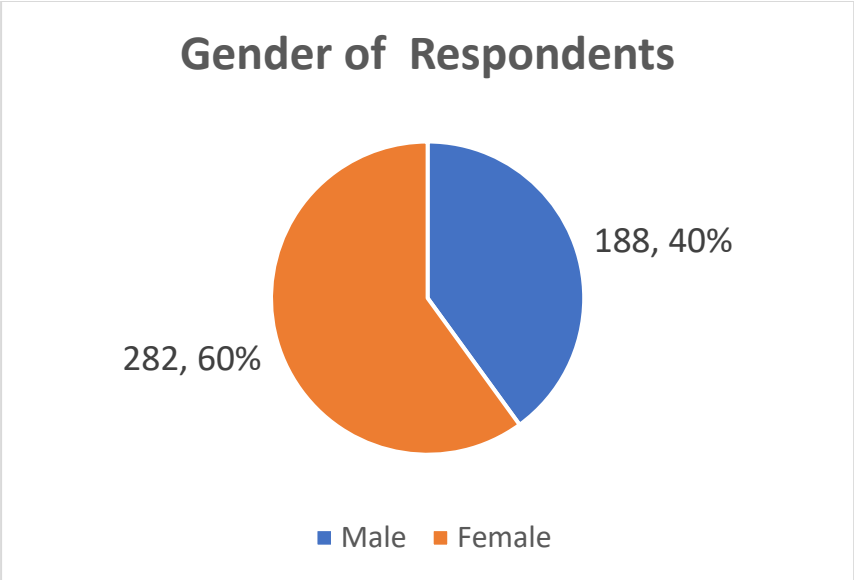
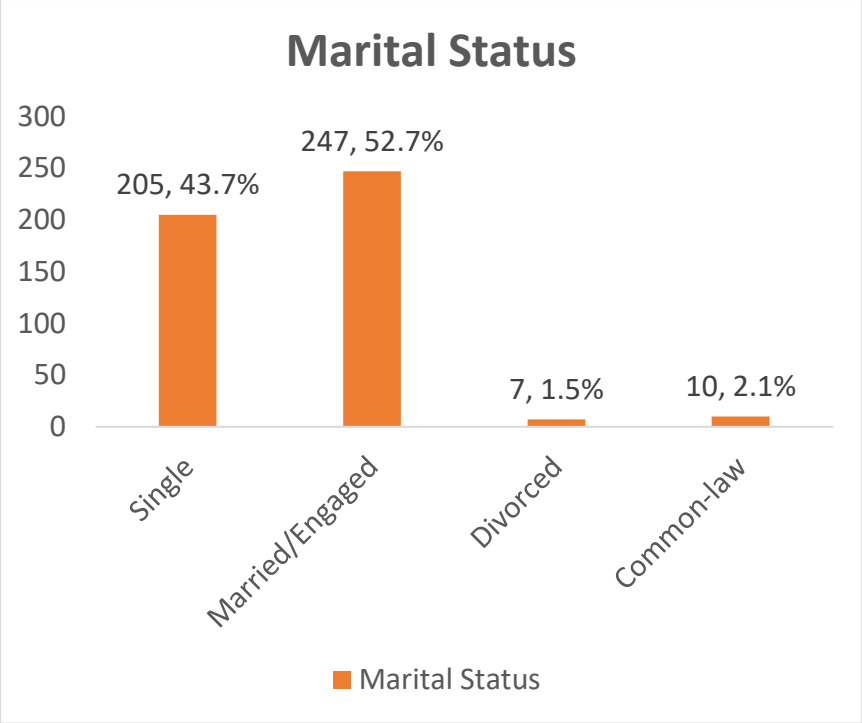


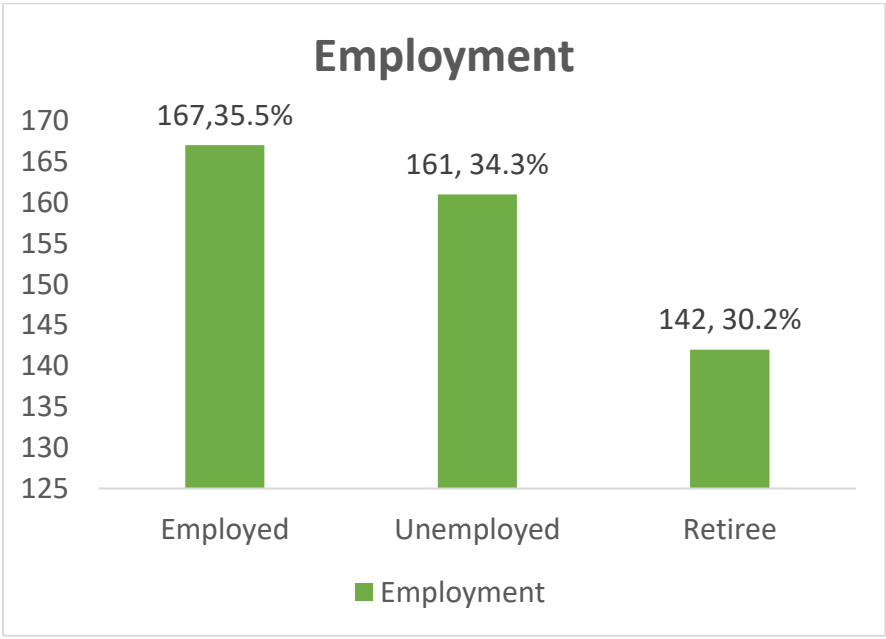
Figure 1 displays the gender composition of the respondents who took part in this study was 282 (60%) female and 188 (40%) male (see figure 1). It is therefore submitted that the data skewed towards a mostly female sample although all respondent responses were considered.

Figure 2: Marital Status of Respondents



Whereas Figure 2 demonstrated that 247 (52.7%) of the sample were married/engaged, while 205 (43.7%) were single. Respondents who were divorced; 7 (1.5%) and in a common law relationship; 10 (2.1%) were in the minority. Based on the findings, most of the sample consisted of single and married individuals.

Figure 3: Employment Status of Respondents



The study gathered data on the employment status of the respondents, as seen in Figure 3, producing 167 (35.5%) employed respondents, 161 (34.3%) unemployed respondents and 142 (30.2%) retired

respondents. Most of the respondents were employed, however the sample appeared to be divided into a third among the categories with unemployed and retired individuals also having high frequencies.

Figure 4: Education Level of Respondents

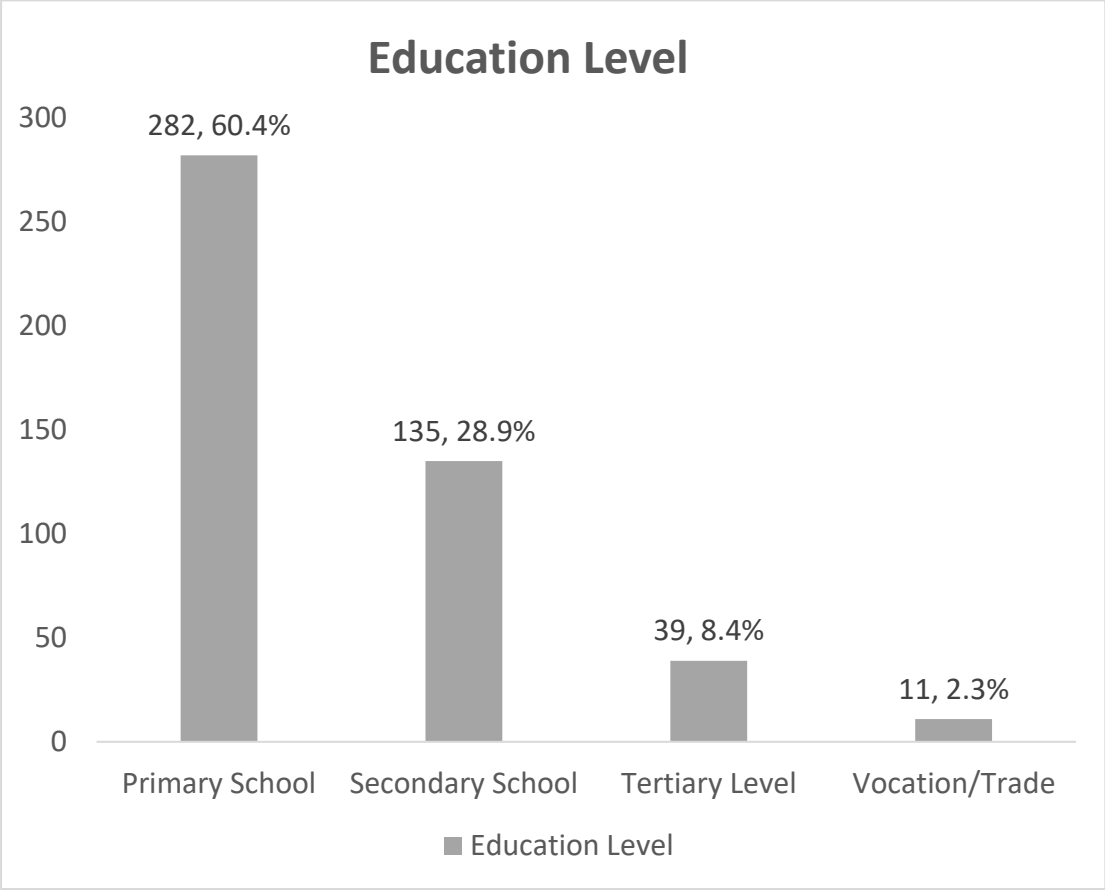


Figure 4 illustrates the education level of respondents consisted of 282 (60.4%) persons with a primary school level education, 135 (28.9%) respondents with a secondary school education, 39 (8.4%) respondents with tertiary level education and 11 (2.3%) respondents with a trade/vocation. The sample provided an indication that the data was skewed towards respondents with a primary school level education.

Demographic Profile (continues)

Figure 5: Income of Respondents

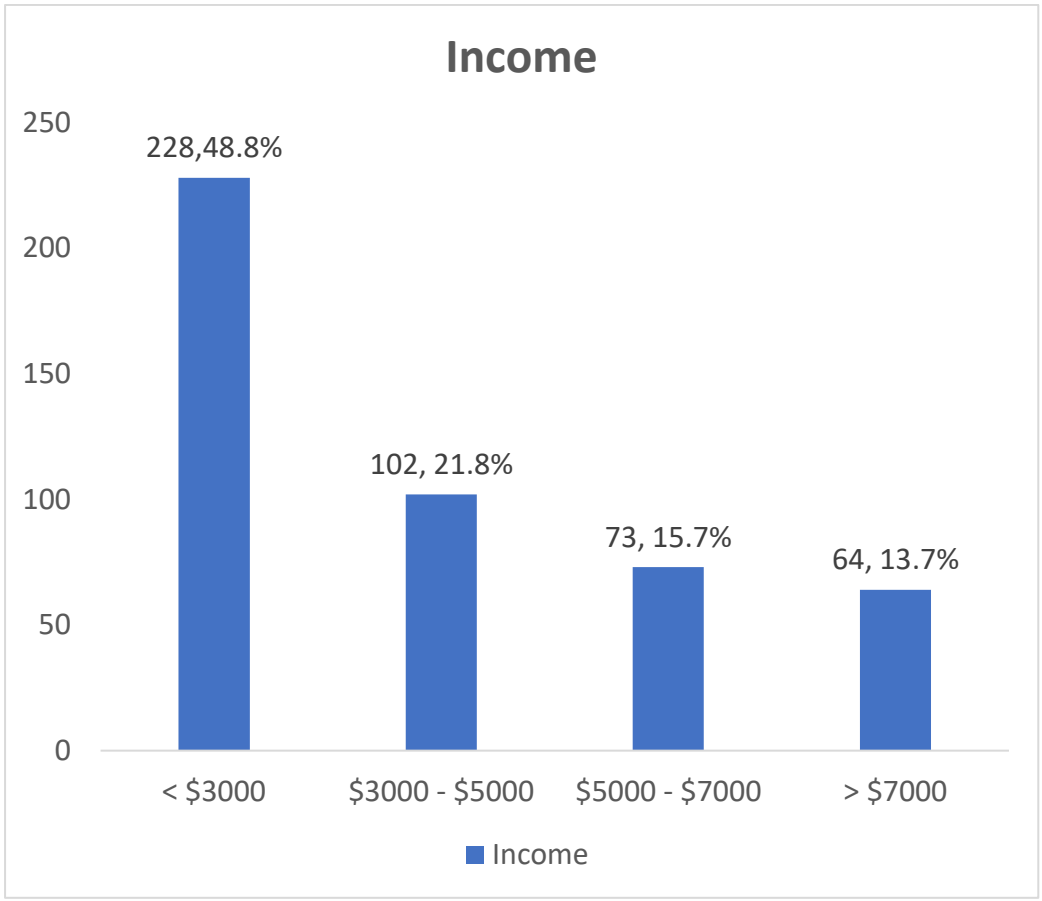


Figure 5 represents the respondents who indicated their incomes during the study which varied by ranging from less than $3,000.00 to more than $7,000.00 a month. 228 (48.8%) of the respondents had incomes less than $3,000.00, 102 (21.8%) respondents had incomes ranging between $3,000.00 - $5,000.00, 73 (15.7%) respondents had incomes ranging between $5000 - $7000 and 64 (13.7%) respondents had incomes more than $7,000.00. The data identified that the sample was skewed towards persons earning less than $3,000.00.

Demographic Profile (continues)

Figure 6: Chronic Diseases Indicated by Respondents

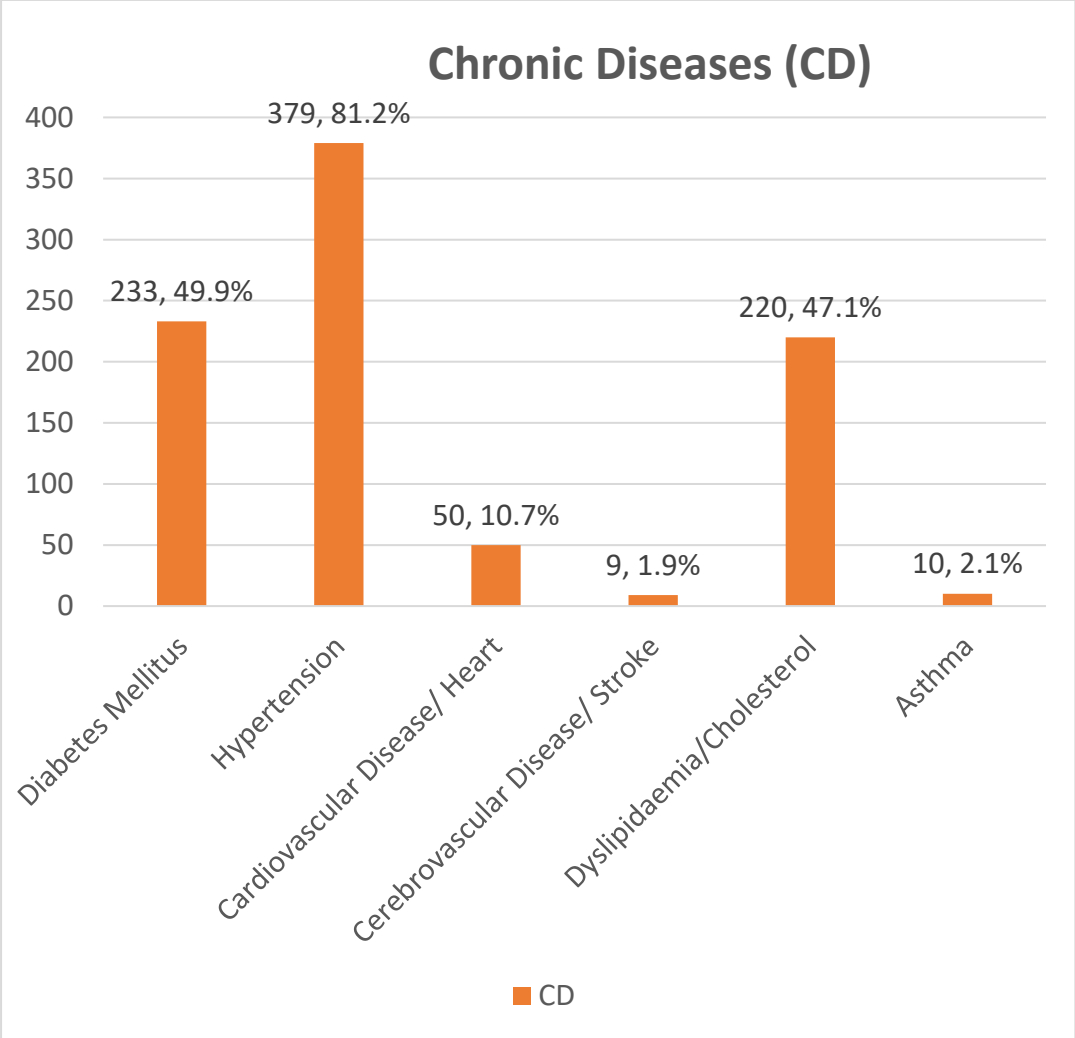
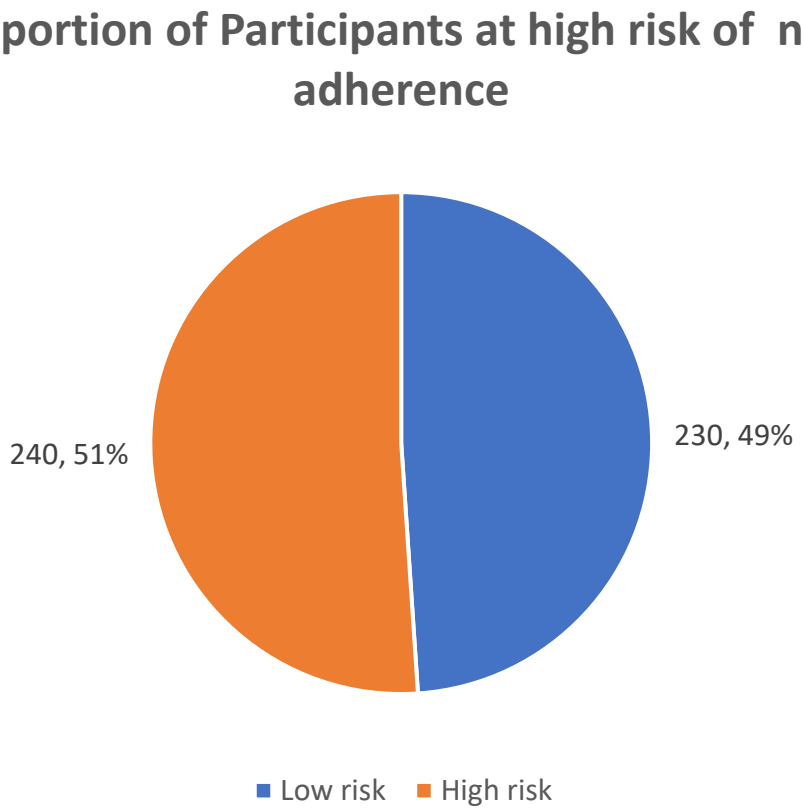


Figure 6 shows how many respondents indicated that they suffered from the following chronic diseases including Diabetes Mellitus 233 (49.9%), Hypertension 379 (81.2%), Cardiovascular Disease/ Heart 50 (10.7%), Cerebrovascular Disease/ Stroke 9 (1.9%), Dyslipidaemia/Cholesterol 220 (47.1%) and Asthma 10 (2.1%). The most prominent disease within the sample was Hypertension, followed by Diabetes Mellitus and Cholesterol. The least prominent among them were Cerebrovascular Disease/Stroke and Asthma.

Research Findings: Clients' Satisfaction vs. Risk of Non-adherence:

Figure 7: Proportion of Participants at High Risk of Non-Adherence



Based on Figure 7, approximately half of the respondents were at low risk of non-adherence 230 (49%) with their medication/s while the other half were at a high risk 240 (51%). This indicated that half of the sample were at risk of not correctly adhering to the medical advice given to them in relation to their generic medications usage.

Table 1: Overall Mean and SD of TSQM Scale Scores

Factors	Mean of Scale Calculation	SD of Scale Calculation
Overall Satisfaction	**65.8**	**10.59**
Effectiveness	**65.7**	**6.89**
Convenience	**66.8**	**5.26**
Knowledge	**3.88**	**.36**
Attitude	**3.18**	**.72**
Non-adherence	**2.10**	**2.018**

Utilizing the Treatment Satisfaction Questionnaire for Medication (TSQM) scale algorithm, the scores for the overall mean and standard deviation were calculated and the findings indicated that from a scale of 0 to 100, the average by the sample was approximately 66 for the overall satisfaction and effectiveness of generic medicines; while the average for convenience of generic medicines was 67, as shown in Table 1.

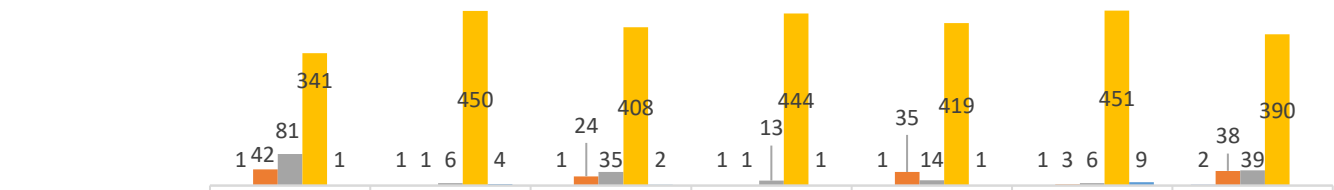
Respondents' knowledge and attitudes towards generic medications were measured using Likert scales, with knowledge having a mean of approximately 4 indicating an overall agreeable with understanding their generic medicines and attitude having a mean of approximately 3 indicating a neutral or indifferent attitude towards generic medicines.

The standard deviation was relatively low for all factors indicating a small outlier presence except for overall satisfaction which had a standard deviation twice as large as effectiveness and convenience indicating the presence of more outliers in this factor.

- FREQUENCIES

Knowledge of Generic Medications

Figure 8: Prevalence of Generic Medications Knowledge among Respondents

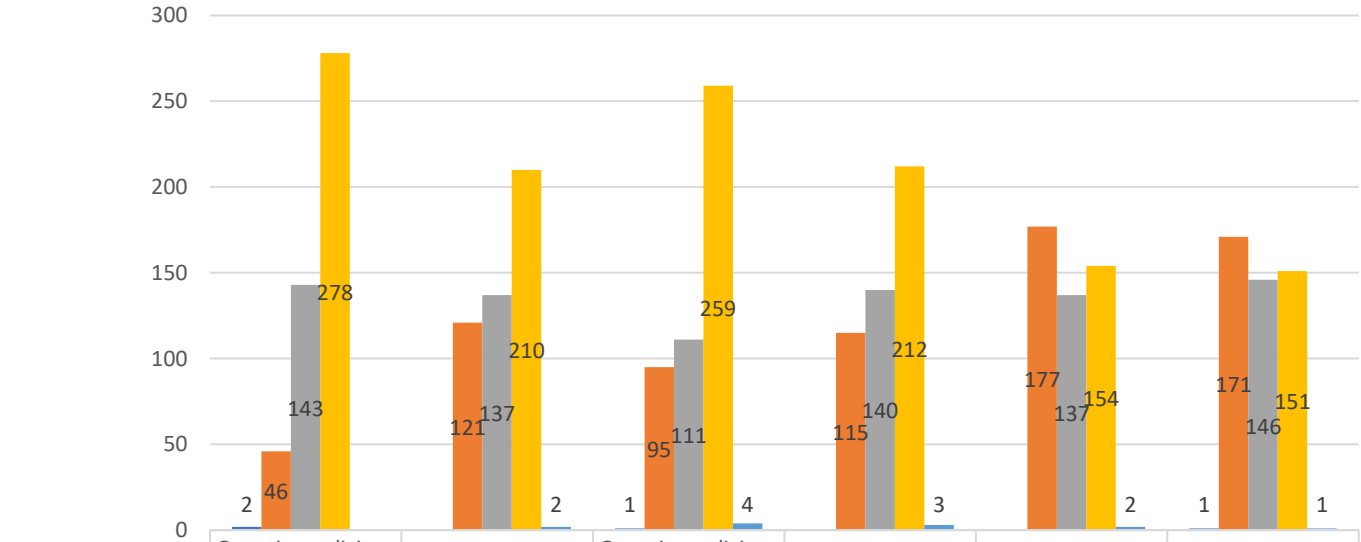


	Generic medicines produce similar adverse reactions as original/brand name medicines.	Generic medicines are cheaper as compared to original/brand name medicines.	Generic medicines provide quality care at an affordable cost.	Generic medicines are important for reducing overall health cost.	Generic medicines are intended to be used the same as original/brand name medicines	Generic medicines need to undergo clinical testing just like original/brand named medicines.	Generic medicines are usually interchangeable with the original/brand name medicines
Strongly Disagree	1	1	1	1	1	1	2
Disagree	42	1	24	1	35	3	38
Neutral	81	6	35	13	14	6	39
Agree	341	450	408	444	419	451	390
Strongly Agree	1	4	2	1	1	9	

The respondents' knowledge was tested on their level of agreeability with generic medicine facts. As seen in Figure 8, it was found that most of the respondents were agreeable with the knowledge that generic medicines produce similar adverse reactions as brand name medicines (342; 73%); generic medicines are cheaper compared to the brand name medicines (454; 97%); generic medicines provide quality care at an affordable cost (410; 87%); generic medicines are important for reducing overall health cost (445; 95%); generic medicines are intended to be used the same as brand name medicines (420; 89%); generic medicines need to undergo clinical testing like brand name medicines (460; 98%) and generic medicines are usually interchangeable with the brand name medicines (390; 83%). Overall, most respondents agreed with the question statement facts about generic medications.

Attitudes toward Generic Medications

Figure 9: Prevalence of Generic Medications Attitudes among Respondents



	Generic medicines take a similar time to act in the body as the original/brand name medicines.	Generic medicines have doubtful efficacy in chronic diseases.	Generic medicines cost less because they are inferior to the original/brand name medicines.	Generic medicines take longer to act in the body.	Generic medicines are not as effective as original/brand name medicines.	Generic medicines are not as safe as the original/brand name medicines.
Strongly Disagree	2		1			1
Disagree	46	121	95	115	177	171
Neutral	143	137	111	140	137	146
Agree	278	210	259	212	154	151
Strongly Agree		2	4	3	2	1

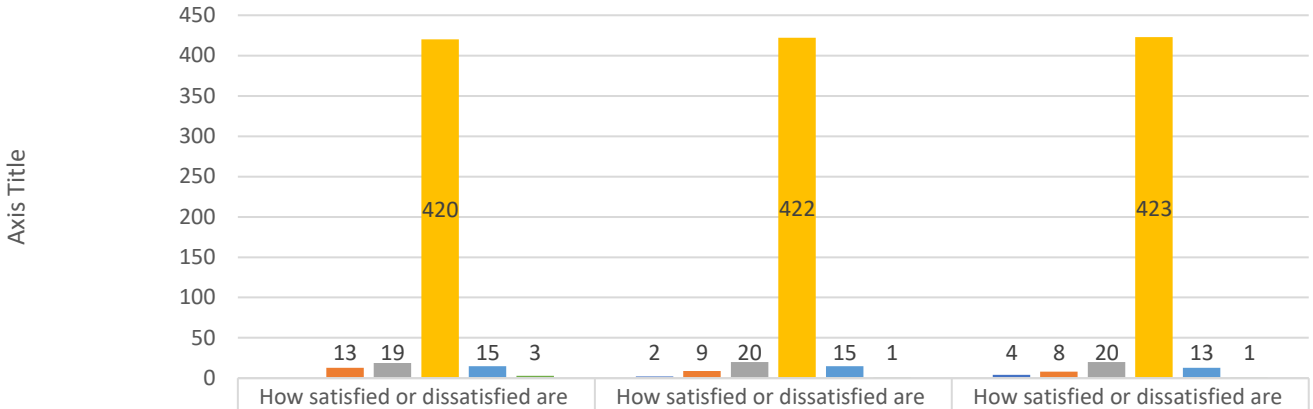
Attitudes exhibited by respondents were measured based on the level of agreeability towards the following opinions on generic medicines. The data displayed in Figure 9 revealed that respondents were generally agreeable with the statements provided indicating that generic medicines take a similar time to

act in the body as the brand name medicines (278; 59%); generic medicines have doubtful efficacy in chronic diseases (212; 45%); generic medicines cost less because they are inferior to the brand name medicines (263; 55%) and generic medicines take longer to act in the body (215; 46%). Most respondents however disagreed on the statements that generic medicines are not as effective as brand name medicines (177; 36%) and generic medicines are not as safe as brand name medicines (172; 37%) indicating that respondents did not agree with the negative statements towards generic medicines.

- TREATMENT SATISFACTION OF GENERIC MEDICATIONS

Effectiveness of Generic Medications

Figure 10: Effectiveness among Respondents

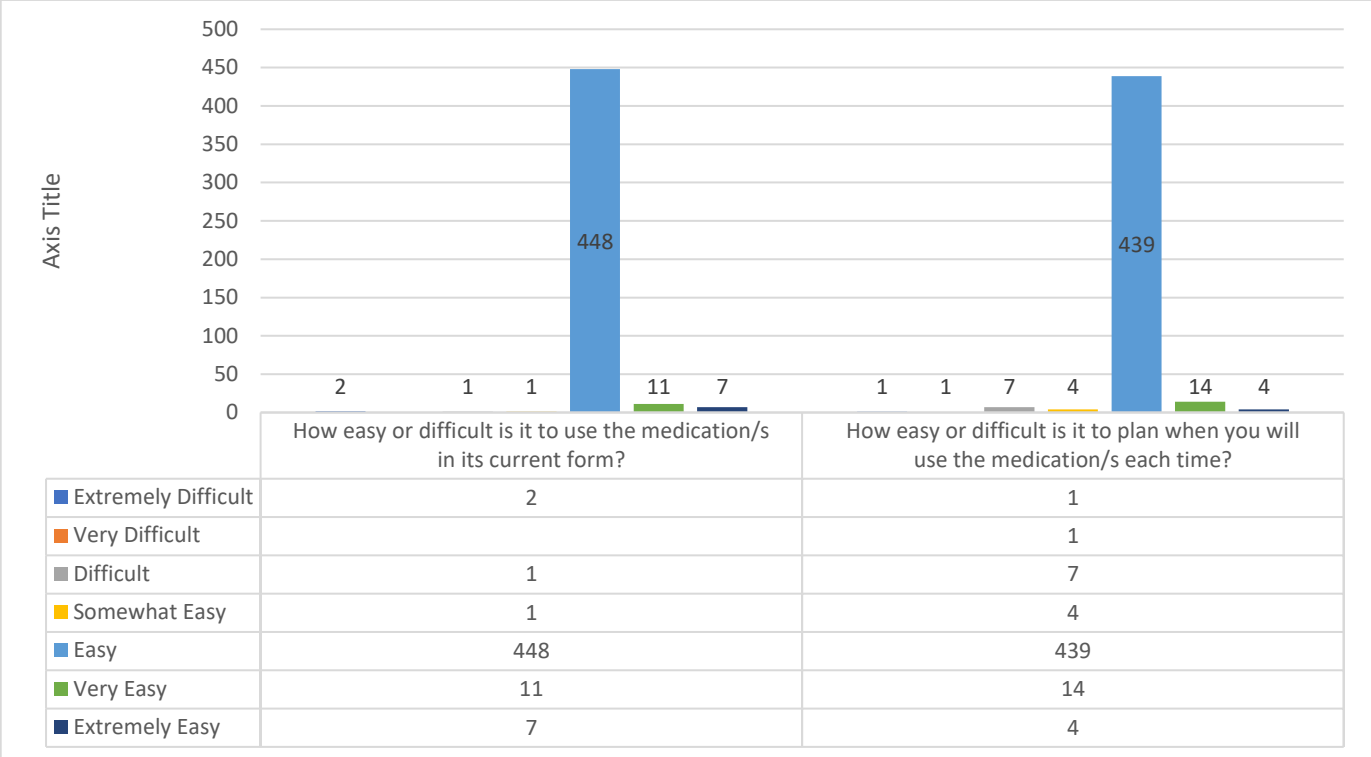


	How satisfied or dissatisfied are you with the ability of the medication/s to prevent or treat your condition?	How satisfied or dissatisfied are you with the way the medication/s relieves your symptoms?	How satisfied or dissatisfied are you with the amount of time it takes the medication/s to start working?
Very Dissatisfied		2	4
Dissatisfied	13	9	8
Somewhat Satisfied	19	20	20
Satisfied	420	422	423
Very Satisfied	15	15	13
Extremely Satisfied	3	1	1

Effectiveness among respondents was gauged utilizing three items from the study instrument. These results, as seen in Figure 10, indicated that the majority of respondents found that generic medications were effective in their: ability to prevent or treat their condition (457; 97%); the way the medication/s relieves their symptoms (458; 97%) and the amount of time it takes the medication/s to start working (457; 97%). None of the respondents chose the option of extremely dissatisfied for any of the above three questions.

Convenience of Generic Medications

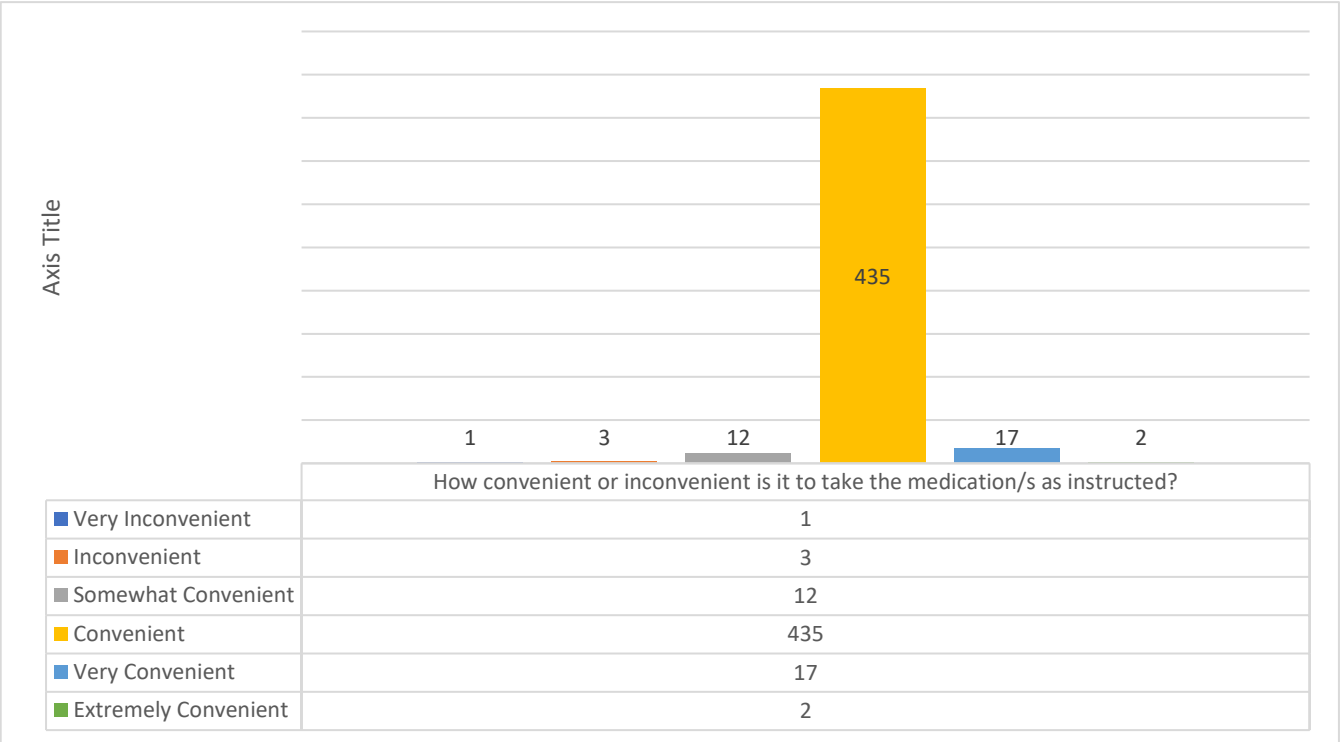
Figure 11.1: Convenient Usage amongst Respondents



	How easy or difficult is it to use the medication/s in its current form?	How easy or difficult is it to plan when you will use the medication/s each time?
Extremely Difficult	2	1
Very Difficult		1
Difficult	1	7
Somewhat Easy	1	4
Easy	448	439
Very Easy	11	14
Extremely Easy	7	4

Factors related to the convenience in use of the generic medication in its current form and in planning to take the medications among respondents was gauged resulting 467 (99%) respondents indicating that the medication was easy to use in its current form and 461 (98.1%) of respondents indicating that is was easy to plan when they utilized their medications as seen above in Figure 11.1.

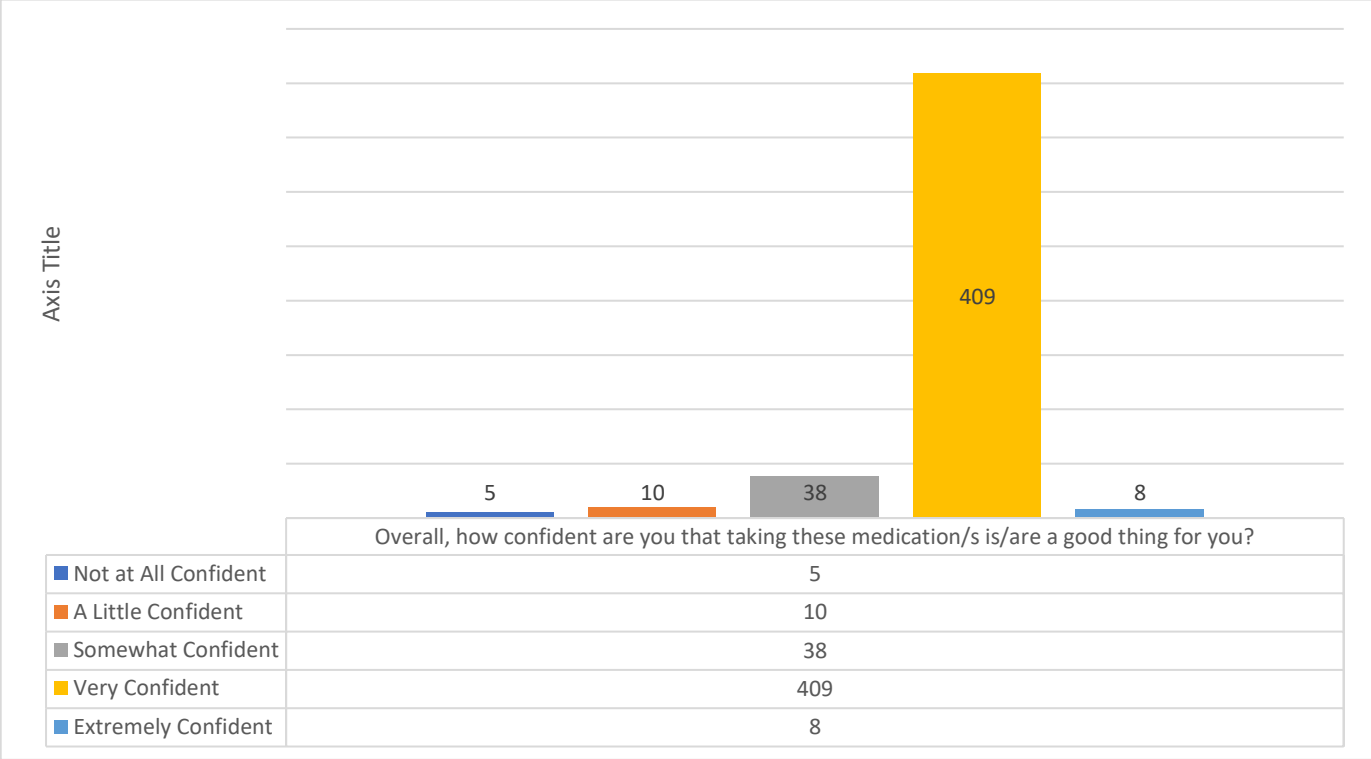
Figure 11.2: Levels of Convenience among Respondents



	How convenient or inconvenient is it to take the medication/s as instructed?
Very Inconvenient	1
Inconvenient	3
Somewhat Convenient	12
Convenient	435
Very Convenient	17
Extremely Convenient	2

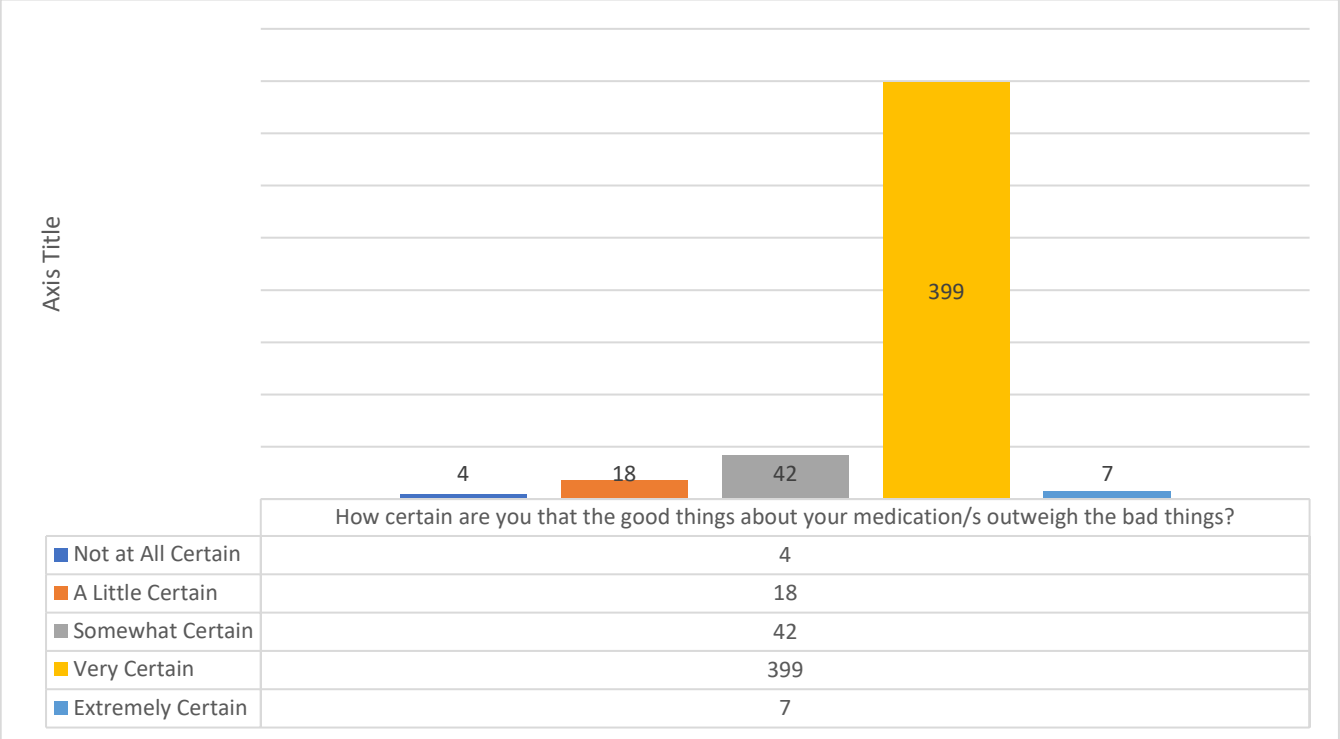
Figure 11.2 shows the overall 466 (99%.1%) of respondents indicated that taking their medication as instructed was convenient.

Figure 12.1: Confidence Levels among Respondents



	Overall, how confident are you that taking these medication/s is/are a good thing for you?
Not at All Confident	5
A Little Confident	10
Somewhat Confident	38
Very Confident	409
Extremely Confident	8

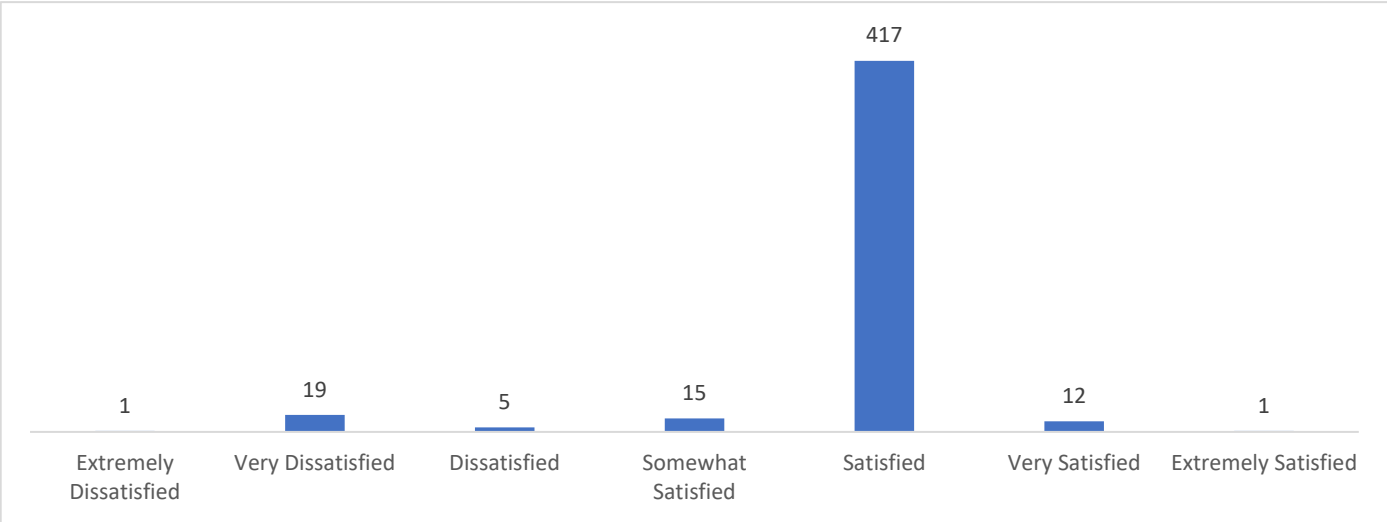
Figure 12.2: Level of Certainty among Respondents Regarding Medication



	How certain are you that the good things about your medication/s outweigh the bad things?
Not at All Certain	4
A Little Certain	18
Somewhat Certain	42
Very Certain	399
Extremely Certain	7

Factors related to the confidence levels among respondents in taking their medication and that taking their medication outweighed any ill effects they may experience were explored. Figure 12.2 represents the results indicated 465 (98.9%) respondents were confident that taking their medication was a good thing and 466 (99.1%) respondents believe that the benefits outweighed the negative effects of their generic medication.

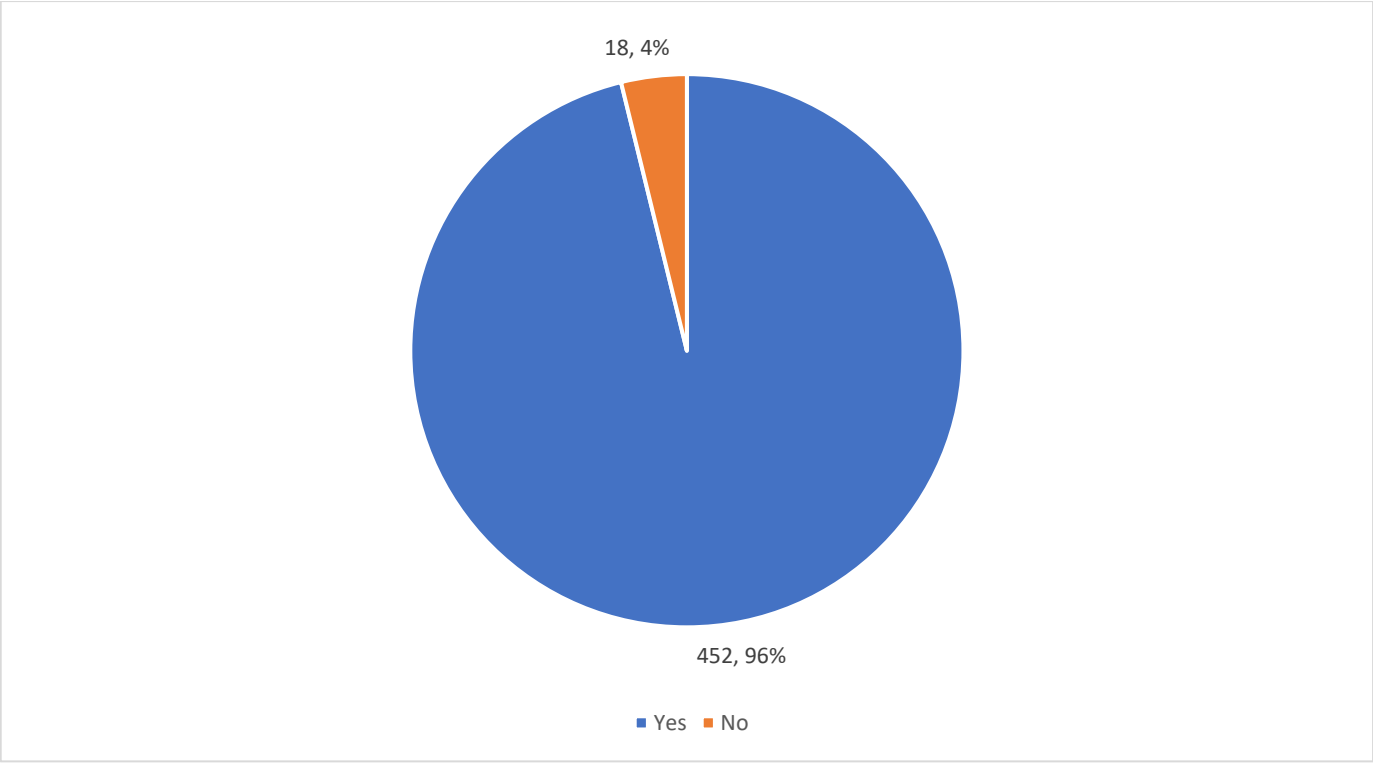
Figure 12.3: Satisfaction among Respondents



Whereas the above Figure 12.3 represents the satisfaction among respondents indicated that the majority of respondents 445 (94.7%) were satisfied with their generic medications taking everything into account.

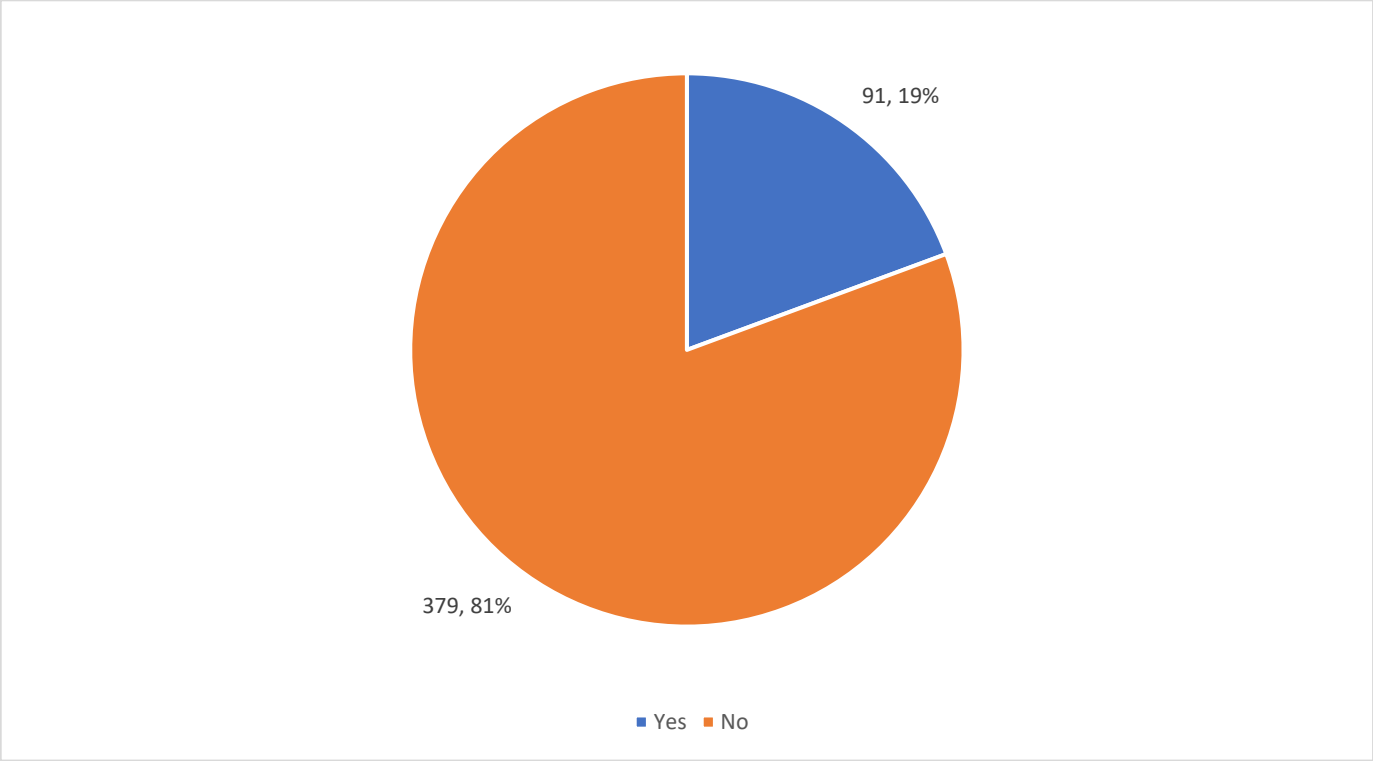
Non-adherence of Generic Medications

Figure 13.1: Do you know what each of your medications is for?



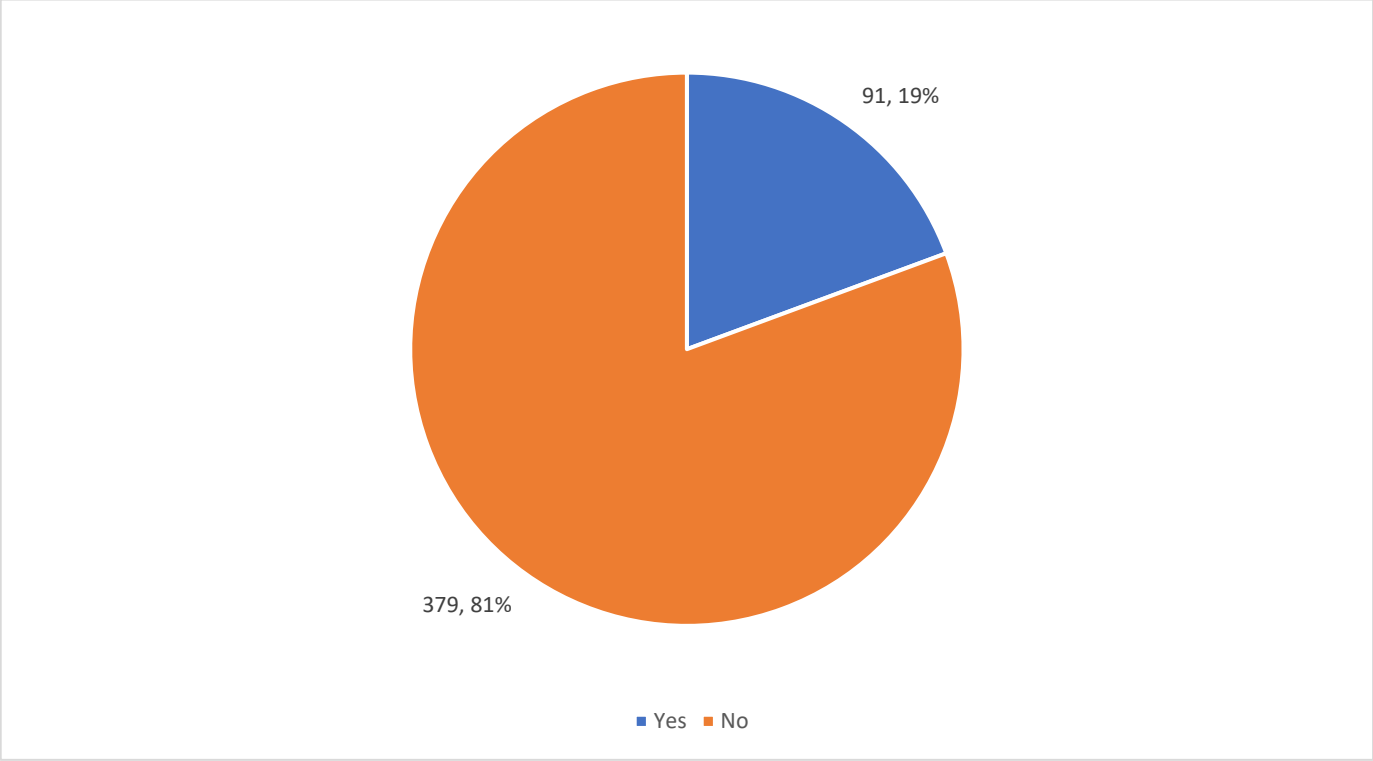
Patients were able to indicate what their medications were used for as represented in Figure 13.1, 452 (96%).

Figure 13.2: Do you ever have trouble remembering when to take your medications?



Approximately 8 in every 10 respondents had no trouble remembering when to take their medications. This is represented by Figure 13.2 where 379 (81%) indicated they had no trouble remembering when to take their medications and 91 (19%) indicated that they did.

Figure 13.3: Do you ever not take medications because you feel you do not need it?



Approximately 20% of the respondents do not take their medication because they do not feel like they need to. As shown in Figure 13.3 with 379 (81%) respondents who do not miss their medication and 91 (19%) respondents who do not feel like they need their medication.

Figure 13.4: Do you ever think that any of your medications are not helping you?

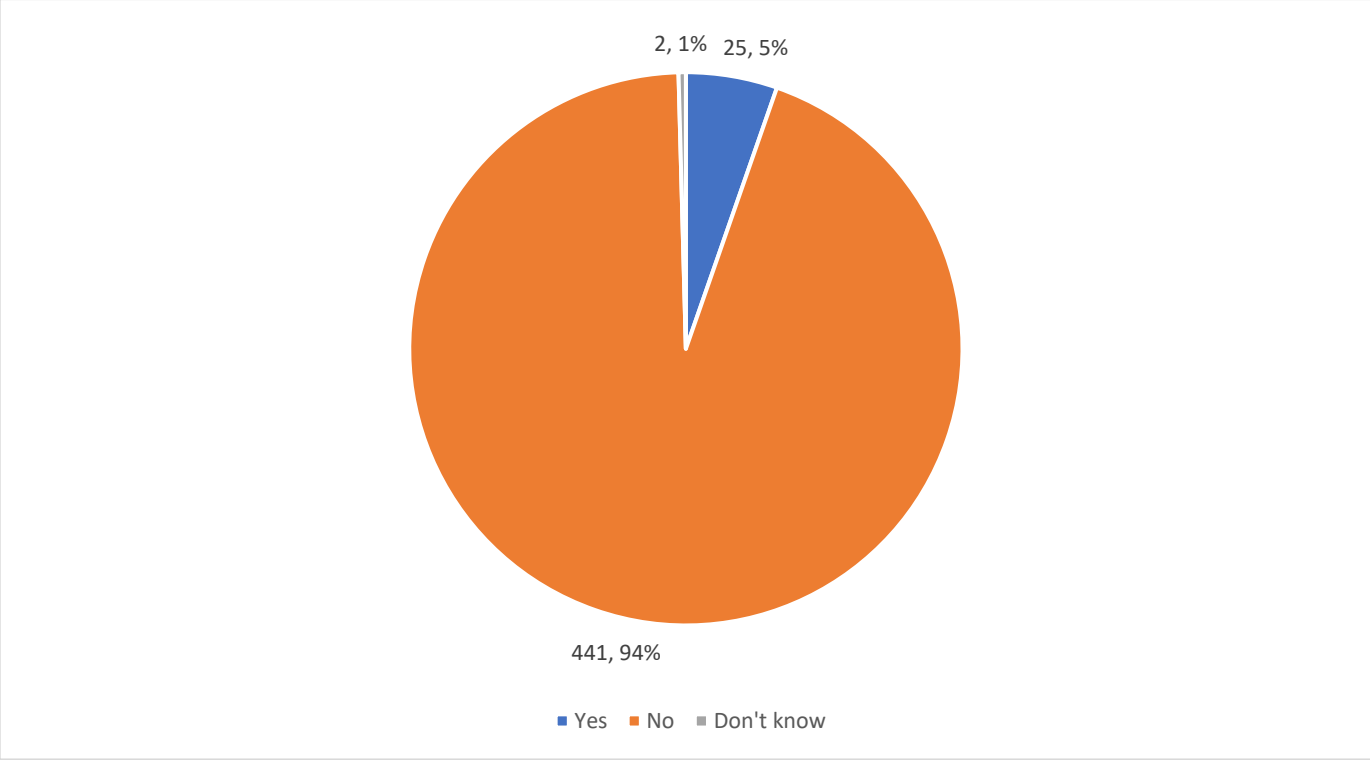
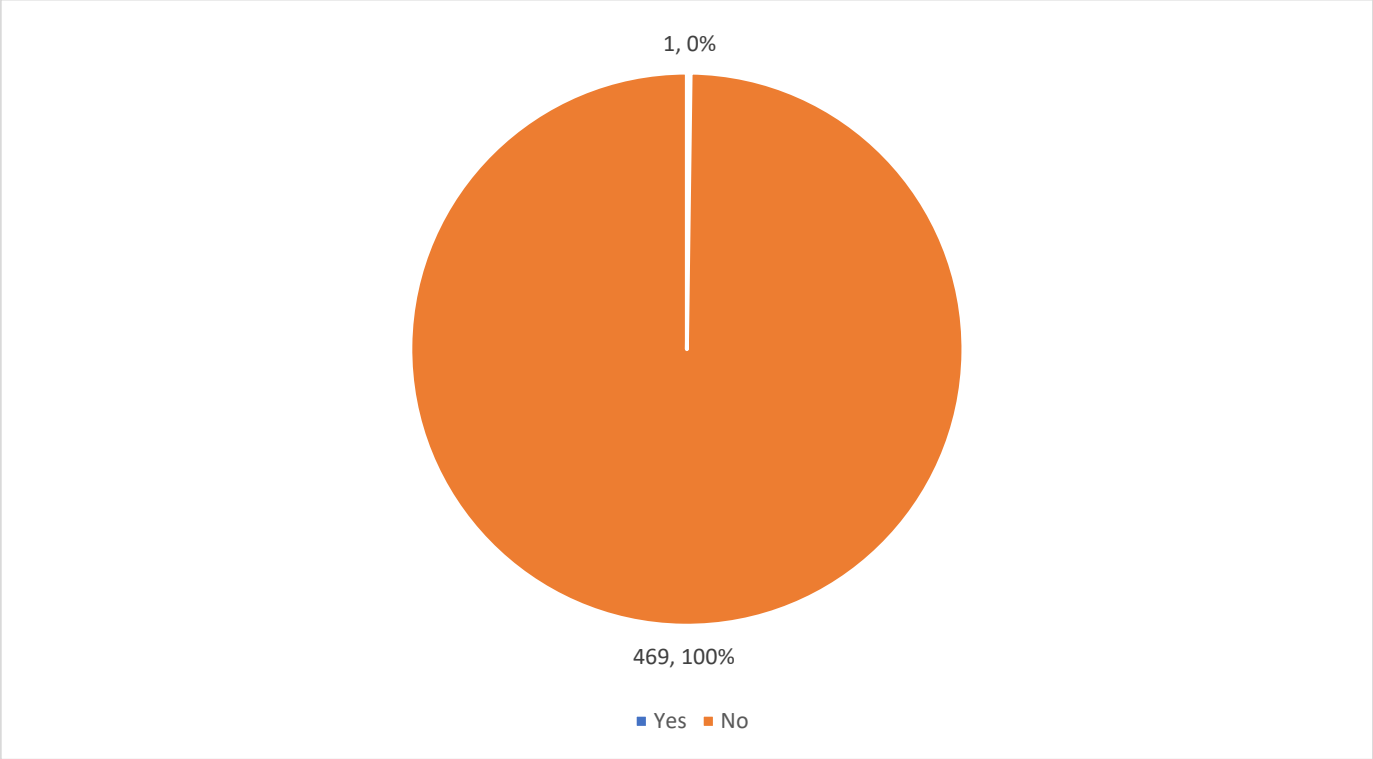


Figure 13.4 indicates that 441 (94%) of respondents think that their medications are helping them. Whereas 25 (5%) of the respondents do not think the medications are helping them.

Figure 13.5: Do you have any physical problems that keep you from taking your medications as prescribed?



As represented by Figure 13.5, all of the 469 (100%) respondents indicated not having any physical problems that would prohibit them from taking their medication as prescribed..

Figure 13.6: Do you think any of your medicines are causing a side effect?

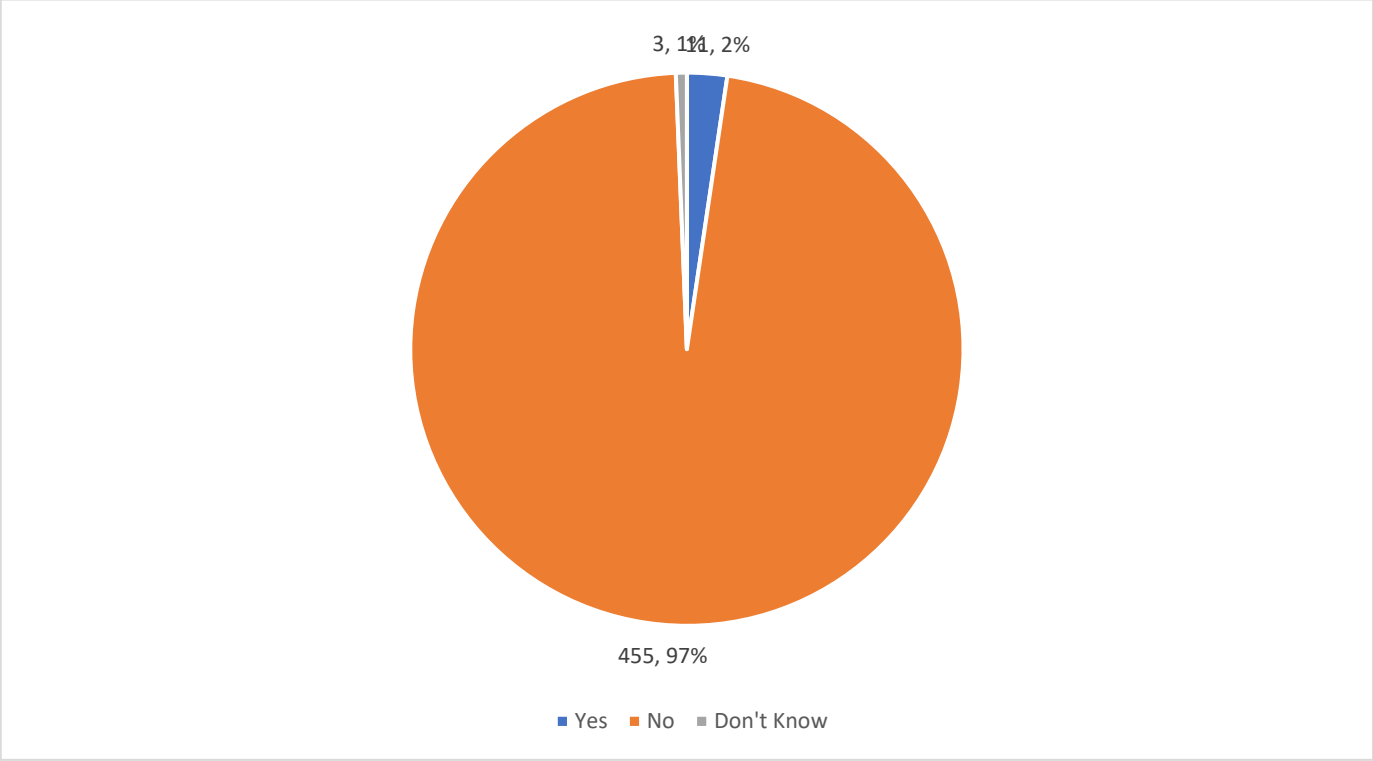
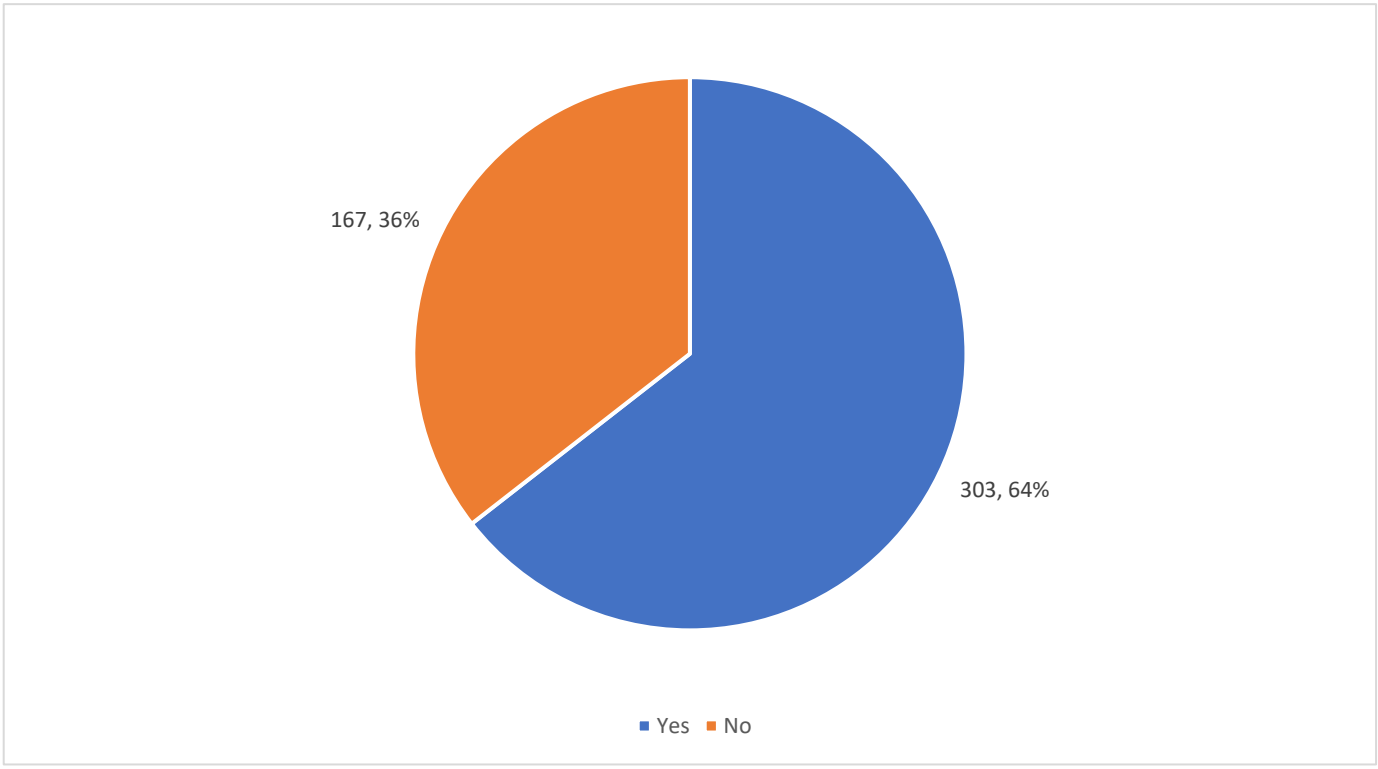


Figure 13.6 indicates that 455(97%) respondents do not think that their medications are causing side effects.

Figure 13.7: Do you know the names of all of your medications?



According to Figure 13.7, approximately 6 in every 10 respondents (303, 64%) know the names of their medication.

Figure 13.8: Do you think that you need all of your medications?

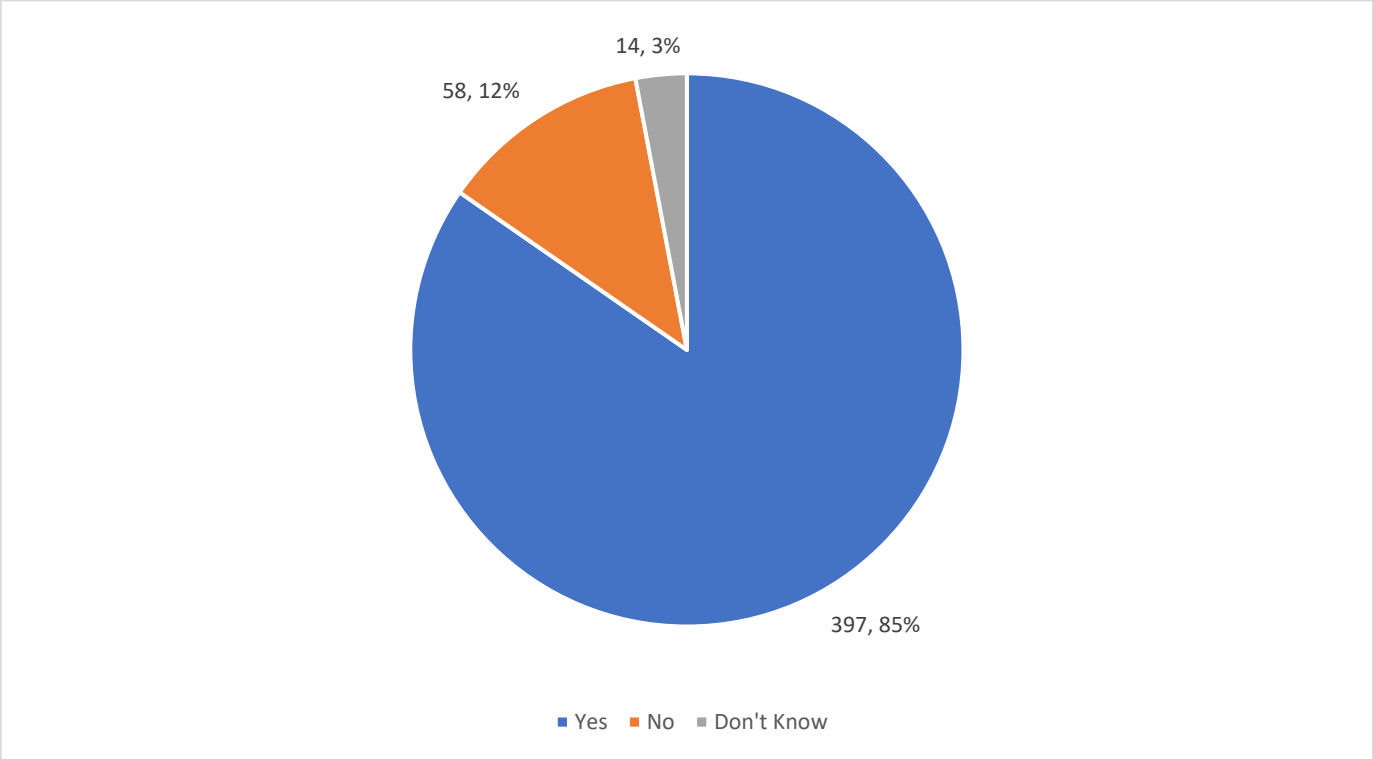
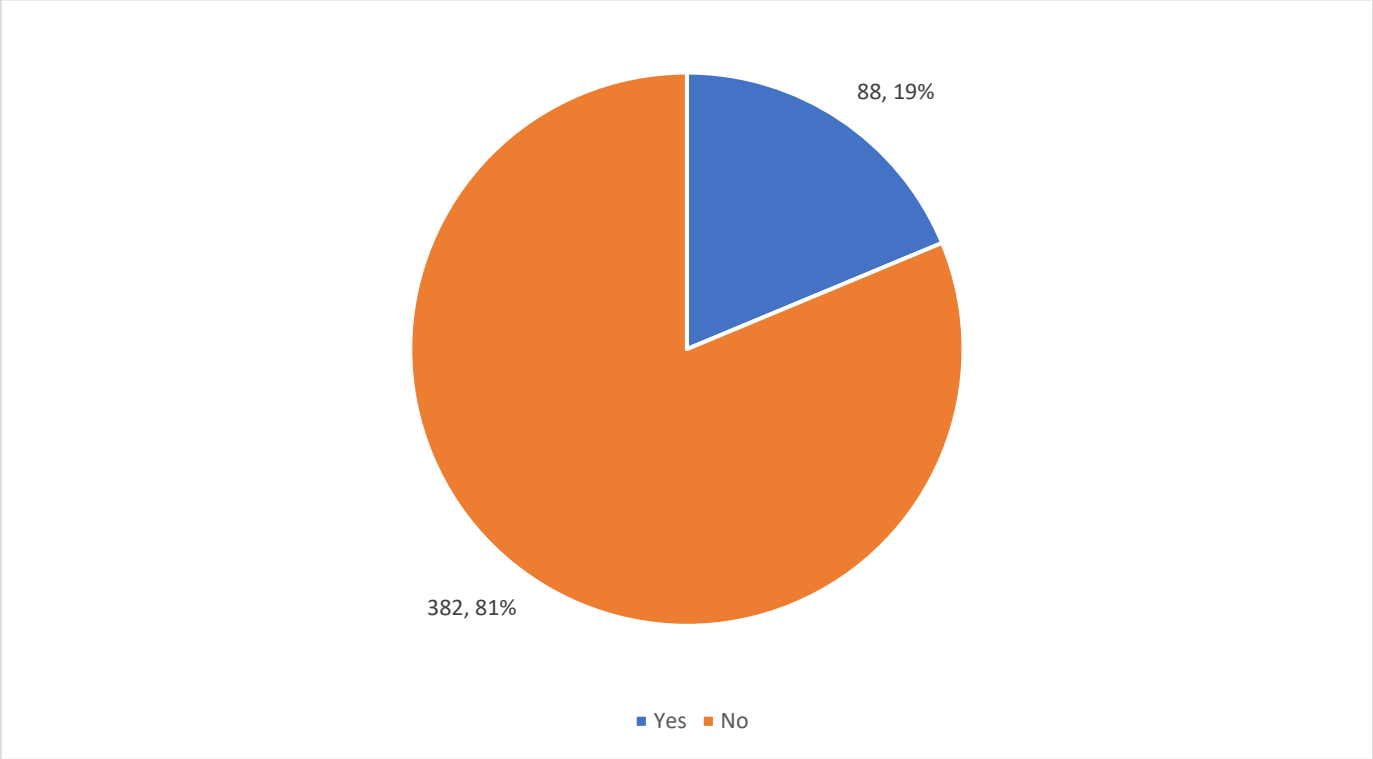


Figure 13.8 indicate that 397 (85%) respondents think that they need all of their medications. While 58 (12%) respondents do not think they need them all, and 14 (3%) do not know if they need all of their medications.

Figure 13.9: In the past 6 months, have you missed getting a refill or a new prescription filled on time?



In the past 6 months, 382 (81%) respondents did not miss getting a refill or a new prescription on time. While 88 (19%) respondents did miss their refill or new prescription pick up on time, according to Figure 13.9.

Figure 13.10: How often do you miss taking a dose of medication?

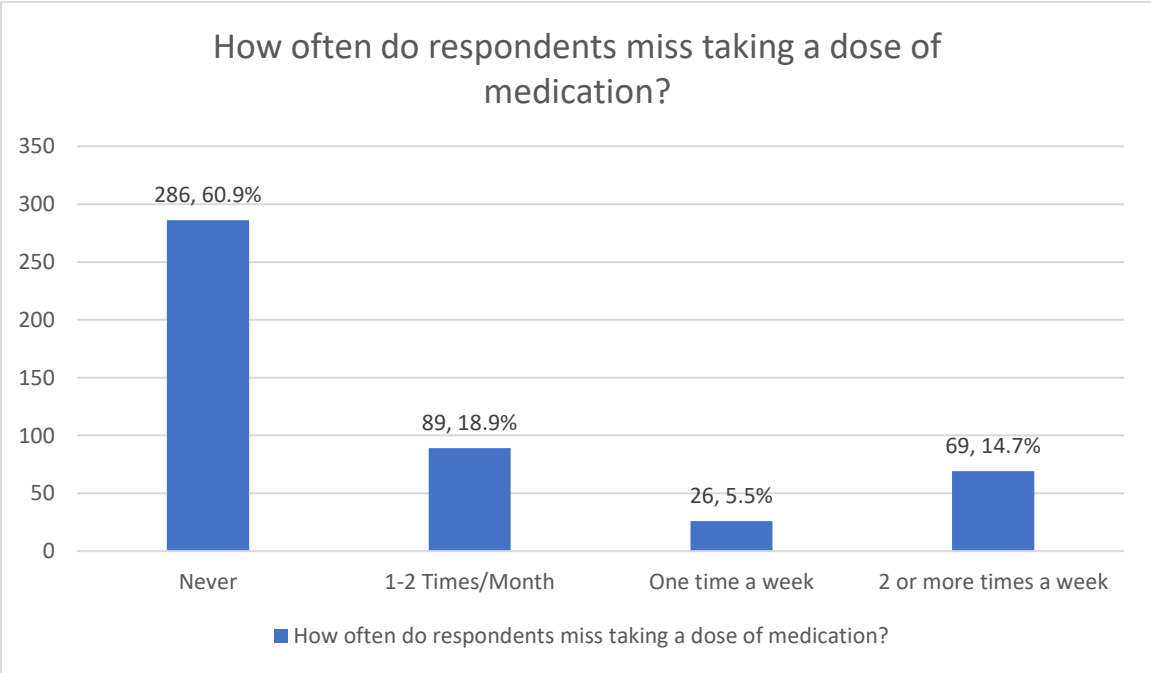
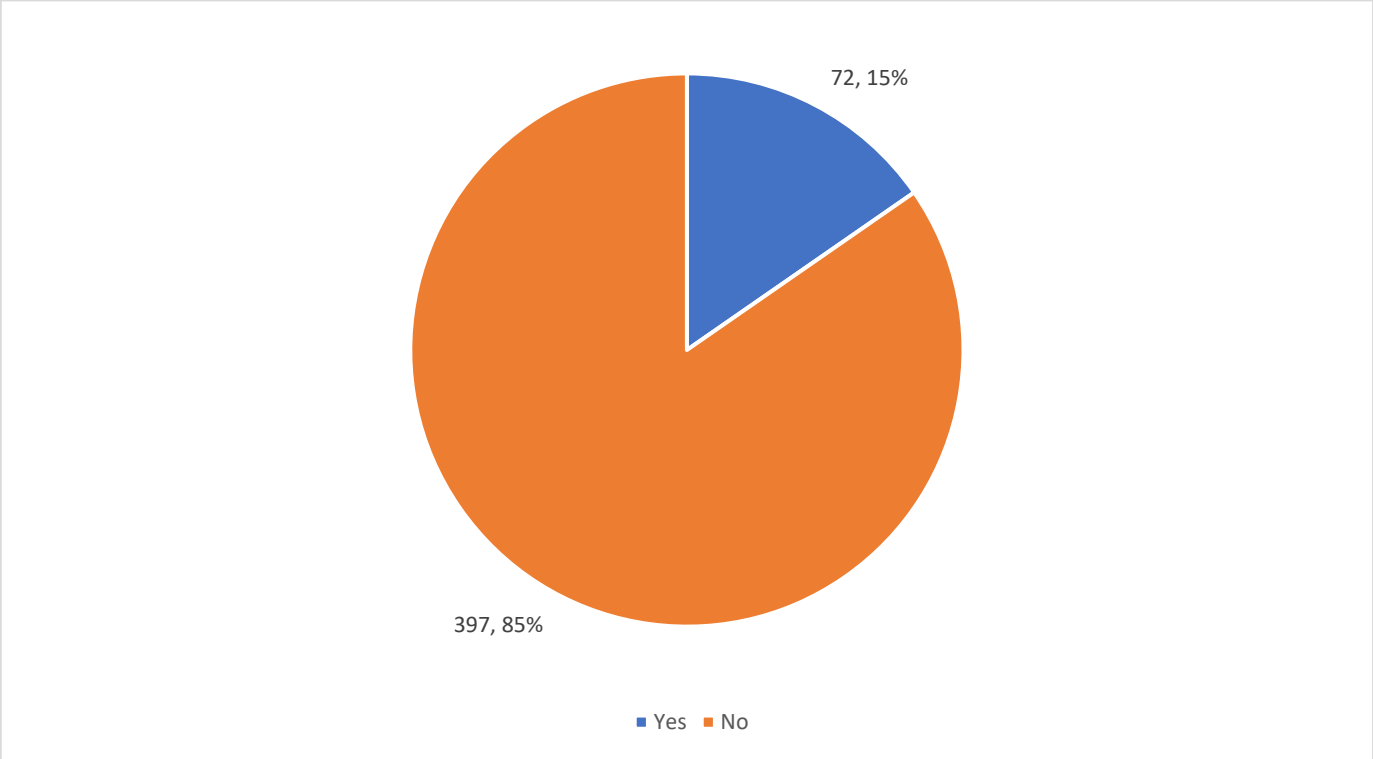


Figure 13.10 indicated that of the respondents who miss taking a dose of medication, 89 (18.9%) miss their medication 1 or 2 times per month, 69 (14.7%) miss their medications 2 or more times per week and 26 (5.5%) miss medications once a week. 286 (60.9%) of respondents never miss their medication.

Figure 13.11: Have you forgotten to take any of your medications within the past week?



397 (85%) respondents indicated that they did not forget to take their medication within the past week, as represented by Figure 13.11.

Figure 13.11a: If YES, which one

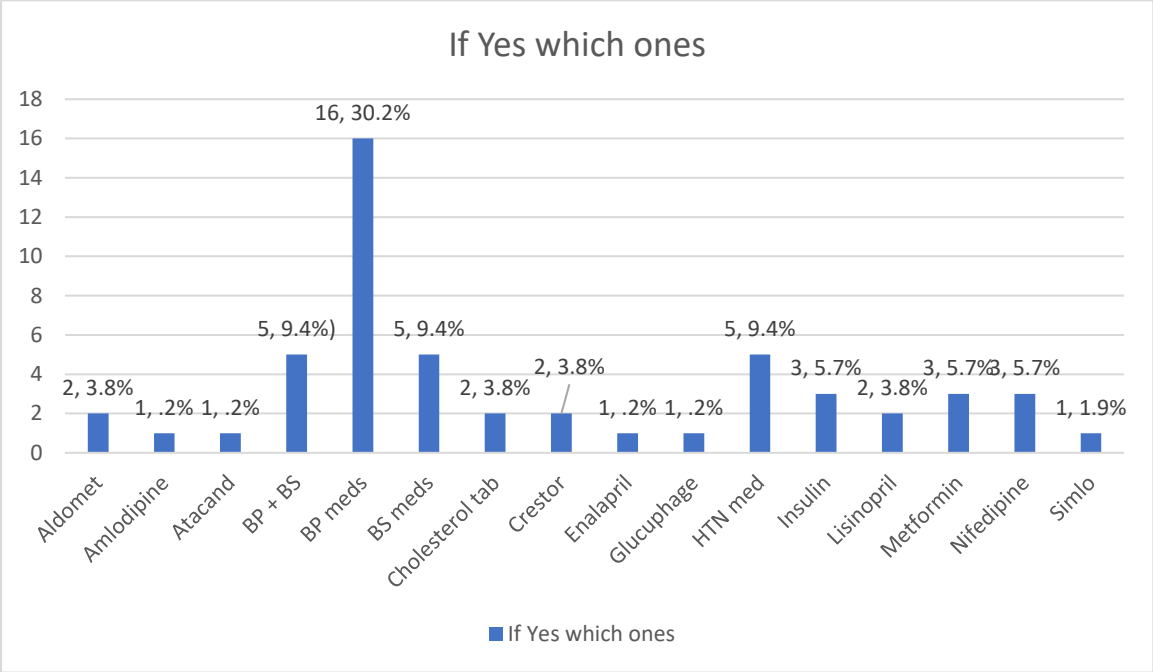


Figure 13.11a shows that the clients would mainly forget to take their blood pressure medications.

Figure 13.11b: How frequent?

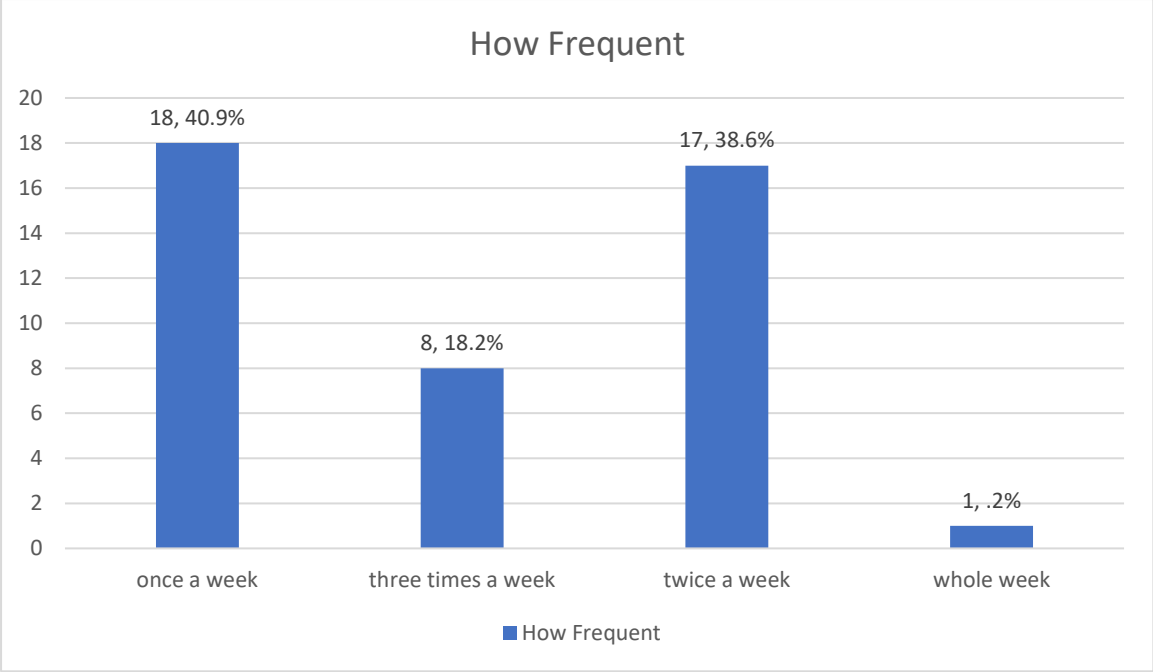
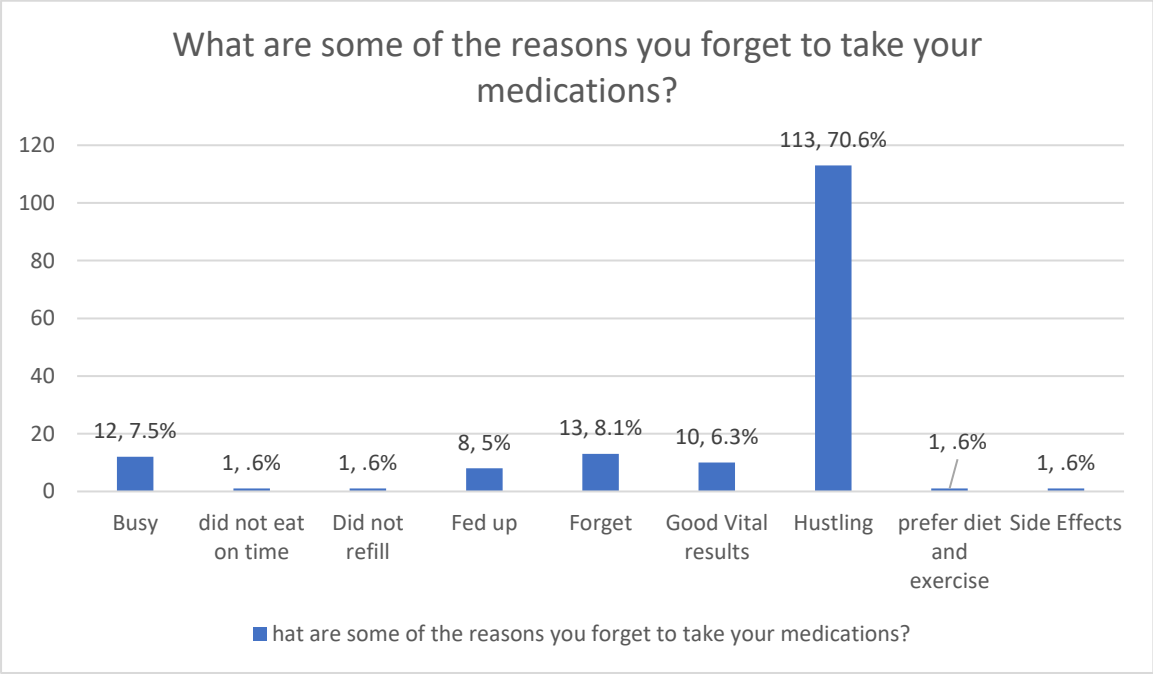


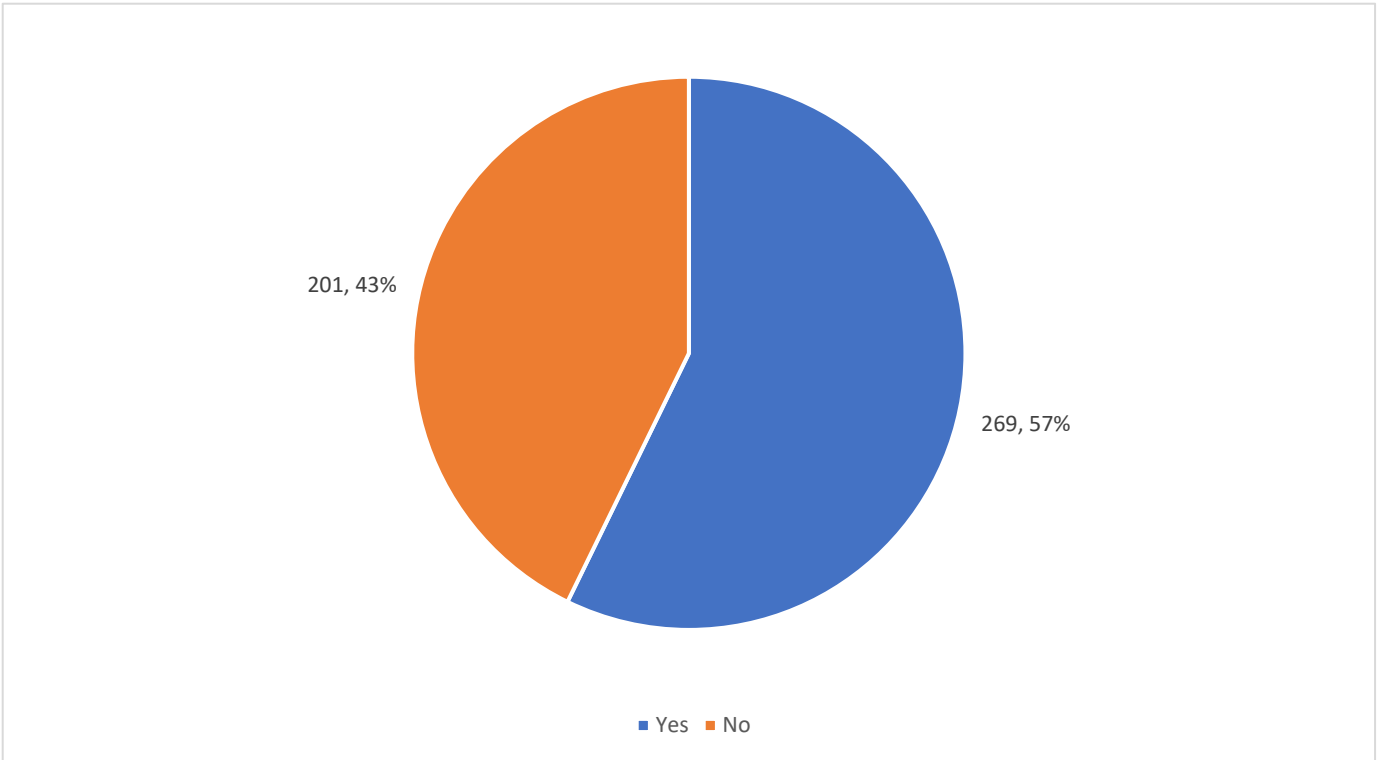
Figure 13.11b indicates that respondents frequently forget their medications once a week (18, 40.9%) and twice a week (17, 38.6%).

Figure 13.11c: What are some of the reasons you forget to take your medications?



Hustling/ busy is the main reason 127 (78.1%) respondents forget to take their medication as illustrated in Figure 13.11c.

Figure 13.12: Is the cost of your medications a concern to you?



Respondents are slightly split in regard to their concern about their medication cost as Figure 13.12 indicated that 269 (57%) respondents are concerned and 201 (43%) are not.

- BIVARATE ANALYSIS

Table 2: Table of Demographic Associations towards Risk of Non-Adherence

Characteristics	Test Statistic	P Value	95% CI Lower Bound	95% CI Higher Bound	Association
Gender	.017	.707	-.098	.119	No
Age	-.137	.002	-.193	-.044	Yes
Marital Status	.009	.525	-.062	.131	No
Employment	-.193	<.005	-.286	-.087	Yes
Education	.137	.002	.058	.221	Yes
Income	.256	<.005	.143	.315	Yes

The above Table 2. shows the bivariate analysis was carried out between the risk of non-adherence among respondents and their demographic characteristics. It was found that there was statistically significant association between age and risk of non-adherence (X(59) = -.137, p = .002); employment status (X(2) = -.193, p <.005; education level (X(3) =.137, p =.002; and monthly income (X(3) = .256, p <.005).

Table 3: Table of Demographic Associations towards Overall Satisfaction

Characteristics	Test Statistic	P Value	95% CI Lower Bound	95% CI Higher Bound	Association
Gender	.008	.959	-.088	.095	No
Age	.049	.982	-.079	.094	No
Marital Status	-.023	.677	-.118	.055	No
Employment	-.033	.562	-.120	.061	No
Education	-.086	.186	-.183	.035	No
Income	.014	.375	-.027	.151	No

Additionally, Table 3 also shows another bivariate analysis that was carried out in order to find if there were any associations between overall satisfaction among respondents and their demographic characteristics. It was found that there was no statistically significant association among all the demographic characteristics and overall satisfaction as all the demographic characteristics had p- values more than .05.

Table 4: Table of Generic Medications Associations towards Risk of Non-Adherence

Factors	Test Statistic	P Value	95% CI Lower Bound	95% CI Higher Bound	Association
Effectiveness	.166	<.0005	.089	.238	Yes
Convenience	.052	.258	-.031	.138	No
Knowledge	.182	<.0005	.116	.260	Yes
Attitudes	-.202	<.005	-.287	-.115	Yes
Overall Satisfaction	.136	.003	.041	.228	Yes

A bivariate analysis was carried out between the risk of non-adherence among respondents and generic medications' factors, as seen in Table 4. It was found that there was statistically significant associations between effectiveness and risk of non-adherence (X(11) = -.166, p <.0005); knowledge (X(4) = -.182, p <.0005; attitude (X(2) =-.202, p <.005; and overall satisfaction (X(468) = .136, p =.003).

Table 5a: Table of Generic Medications Associations towards Overall Satisfaction

Factors	Test Statistic	P Value	95% CI Lower Bound	95% CI Higher Bound	Association
Effectiveness	.661	<.0005	.548	.776	Yes
Convenience	.394	<.0005	.149	.568	Yes
Knowledge	.158	.001	.027	.247	Yes
Attitudes	-.040	.391	-.117	.049	No
Risk of Non-Adherence	.136	.003	.046	.206	Yes

A bivariate analysis was performed in order to find if there were any associations between overall satisfaction among respondents and generic medications factors. Based on Table 5, it was found that there was statistically significant associations between effectiveness (X(468) = .661, p <.0005); convenience (X(469) =.394, p <.0005; knowledge (X(469) =.158, p =.001; and increased risk of non-adherence (X(468) = .136, p =.003).

Table 5.b: Table of Non-Adherence Associations towards Overall Satisfaction

Factors	Test Statistic	P Value	95% CI Lower Bound	95% CI Higher Bound	Association
Do you know what each of your medications is for?	1.459	.145	-1.286	8.706	No
Do you ever have trouble remembering when to take your medications?	1.449	.148	-.637	4.216	No
Do you ever not take medications because you feel you do not need it?	4.264	<.0005	2.791	7.564	Yes
Do you ever think that any of your medications are not helping you?	9.043	<.0005	13.556	21.083	Yes
Do you have any physical problems that keep you from taking your medications as prescribed?	1.228	.220	-7.814	33.832	No
Do you think any of your medicines are causing a side effect?	6.026	<.0005	12.322	24.249	Yes
Do you know the names of all of your medications?	-2.068	.039	-4.103	-.105	Yes
Do you think that you need all of your medications?	3.988	<.0005	2.911	8.567	Yes
In the past 6 months, have you missed getting a refill or a new prescription filled on time?	1.874	.062	-.114	4.794	No
How often do you miss taking a dose of medication?	4.454	<.0005	2.969	7.657	Yes
Have you forgotten to take any of your medications within the past week?	1.185	.237	-1.059	4.275	No
Is the cost of your medications a concern to you?	1.743	.082	-.218	3.654	No

A bivariate analysis was performed in order to find if there were any associations between overall satisfaction among respondents and non-adherence factors. Based on Table 5.b , it was found that there

was statistically significant associations between respondents: who do not take their medications because they do not feel they need it (t(468) = 4.264, p <.0005); who think that their medications are not helping them (t(464) =9.043, p <.0005; who experience side effects from their medications (t(464) = 6.026, p <.0005); who know all the names of their medications (t(468) = -2.068, p .039); who think that they need all their medications (t (453) = 3.988, p <.0005) and who often miss taking their medications (t(468) = 4.454, p <.0005).

- LINEAR REGRESSION

Table 6 a: Linear Regression Analysis

Coefficients										
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Tolerance	VIF
1	(Constant)	-7.910	5.800		-1.364	.173	-19.307	3.487		
	Risk of Non-Adherence	.531	.748	.025	.710	.478	-.939	2.001	.949	1.054
	Effectiveness	.935	.063	.612	14.851	.000	.811	1.058	.706	1.417
	Convenience	.172	.080	.086	2.139	.033	.014	.329	.744	1.344
	Knowledge	.152	1.052	.005	.145	.885	-1.914	2.219	.926	1.080

a. Dependent Variable: Overall Satisfaction

A linear regression analysis was carried out to determine the factors that had an impact on the overall satisfaction of respondents depicted in Table 6. The results indicated that for every increase in the overall satisfaction score, it was expected that the effectiveness and convenience of generic medications increased by an average of .935 and .172 respectively.

Table 6.b: Linear Regression Analysis – Non-Adherence factors

Coefficients									
Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Collinearity Statistics	
	B	Std. Error	Beta			Lower Bound	Upper Bound	Tolerance	VIF
(Constant)	67.209	.519		129.620	.000	66.190	68.228		
Do you ever not take medications because you feel you do not need it?	-1.074	1.239	-.043	-.866	.387	-3.510	1.362	.692	1.445
Do you ever think that any of your medications are not helping you?	-16.960	1.927	-.376	-8.803	.000	-20.746	-13.173	.922	1.085
Do you think any of your medicines are causing a side effect?	-13.679	2.840	-.201	-4.816	.000	-19.261	-8.097	.962	1.039
Do you know the names of all of your medications?	2.755	.834	.137	3.304	.001	1.117	4.394	.971	1.030
Do you think that you need all of your medications?	-2.572	1.328	-.089	-1.936	.053	-5.182	.039	.792	1.262
How often do you miss taking a dose of medication?	-1.329	1.163	-.055	-1.143	.254	-3.614	.956	.729	1.372

a. Dependent Variable: Overall Satisfaction

A linear regression analysis was carried out to determine the non- adherence factors that had an impact on the overall satisfaction of respondents depicted in Table 6.b. The results indicated that for every increase in the overall satisfaction score, it was expected that respondents who did not think their medications were helping decreased by -16.960; respondents who thought their medications were causing side effects were decreased by -13.679; and respondents who knew the names of all their medications increased by 2.755.

- LOGISTIC REGRESSION

Table 7: Logistic Regression Analysis

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	D2	.008	.012	.422	1	.516	1.008	.984	1.032
	D4			11.974	2	.003			
	D4(1)	.752	.353	4.542	1	.033	2.121	1.062	4.235
	D4(2)	1.246	.366	11.616	1	.001	3.476	1.698	7.115
	D5			5.788	3	.122			
	D5(1)	.191	.293	.424	1	.515	1.210	.681	2.150
	D5(2)	-.689	.511	1.820	1	.177	.502	.185	1.366
	D5(3)	1.054	.709	2.212	1	.137	2.870	.715	11.516
	D6			17.156	3	.001			
	D6(1)	.908	.339	7.186	1	.007	2.480	1.277	4.819
	D6(2)	1.320	.402	10.766	1	.001	3.743	1.701	8.235
	D6(3)	1.957	.505	15.040	1	.000	7.076	2.632	19.023
	Effectiveness	.034	.023	2.261	1	.133	1.034	.990	1.081
	Overall_Satisfaction	.013	.014	.919	1	.338	1.013	.986	1.041
	Knowledge	.813	.355	5.235	1	.022	2.254	1.124	4.520
	Attitudes	-.430	.152	7.996	1	.005	.650	.483	.876
	Constant	-6.813	2.112	10.406	1	.001	.001		

a. Variable(s) entered on step 1: D2, D4, D5, D6, Effectiveness, Overall_Satisfaction, Knowledge, Attitudes.

A logistic regression analysis was carried out to determine the factors that had an impact on the increased risk of non-adherence of respondents towards their generic medications illustrated in Table 7. The results indicated that the respondents' employment status, monthly income, attitudes and knowledge had an impact on the increased risk of non-adherence. Respondents were 2.121 times more likely to be at a low risk if they were employed and 3.476 times more likely to be at a low risk if they were unemployed compared to retirees. Persons with monthly incomes above $3,000.00 were more likely to be at a low risk of non-adherence than those with monthly incomes of <$3,000.00. It was found that respondents with attitude towards generic medicine were at a higher risk of non-adherence and respondent's knowledge of their generic medicines increased the likelihood of a low risk of non-adherence by 2.254.

DISCUSSION OF RESULTS

- INTRODUCTION

The results demonstrated in the previous chapter were analysed in-keeping with the objectives and research questions set within this paper. The data presented was an indication of the demographic composition of chronic-diseased clients who take generic medications for their conditions and provided a summarised view of the associations between demographic characteristics and generic medications' factors. The impact of these factors on the overall satisfaction of clients towards generic medications were also explored in order to provide an indication of the type of effect each factor had on overall satisfaction.

- DEMOGRAPHIC PROFILE

The demographic profile indicated that the sample of chronic-diseased clients being treated with generic medications was predominantly a female driven sample with 6 in every 10 in the sample being female, (***Figure 1***). However, the marital status of the sample population was primarily married or engaged with more than half of the sample falling into this category (***Figure 2***). There was also a significant number of single clients within the sample. Whereas the employment status of the sample population was approximately broken into a third for employed, one-third unemployed and one-third retirees (***Figure 3***). Furthermore, the education level achieved by most of the sample was primary with 6 in every 10 respondents falling into this category (***Figure 4***). In regard to the income, most of the sample population also had a monthly income of less than $3,000.00 with approximately half of the sample making this amount (***Figure 5***).

Chronic-disease wise, the primary chronic disease conditions afflicting the sample appeared to be Hypertension with 8 in every 10 respondents reporting this ailment. This was followed by Diabetes Mellitus which approximately half of the sample suffered from, followed by Cholesterol (***Figure 6***). It was further found that the sample population was skewed towards respondents with a primary school education and persons making less than $3,000.00, but traditionally consisted of demographic attributes among persons suffering from chronic diseases with a mean age of 61 (years) and the prevalence of hypertension within the sample population.

These research results would provide a background for which researchers can identify the reasons why results may differ from other papers with findings with a normalized distribution within education and monthly income and would help provide context as to why overall satisfaction and increased risk of non-adherence were impacted by factors related to generic medications.

Various factors were explored within this paper, namely, generic medications' effectiveness, convenience, knowledge, and attitudes can positively and/or negatively impact on non-adherence and overall satisfaction on the use of generic medications, with the researcher placing some emphasis on the risk of non-adherence.

The author found that the risk of non-adherence amongst the respondents was divided to approximately 50% between respondents indicating that half the sample population were at a high risk of non-adherence (***Figure 7***). However, the author opined that this did not mean that they were non-adherent but based on the data calculated with the use of the algorithm findings herein. More importantly, it would appear that there was a risk of high non-adherence based on the certain behaviours exhibited by respondents placing them in a position of high risk. Interestingly, reviewed literature has showed that medical professionals are aware of these behaviours and should be able to utilise this data to reinforce good adherence practices within chronic-diseased clients.

The overall mean value based on the collected data for attitudes and knowledge, as seen in Table 1, exhibited by respondents indicated that participants had an indifferent attitude towards their generic medications with the similar times medications act on a respondent's physical body (health and wellbeing). The researched received agreeable feedback from participants and the lack of effectiveness compared to brand medicines providing a divergent view from the majority of the sample population. Although, the knowledge aspect displayed by the sample population indicated a level of agreeability with the facts on their generic medications, unlike the study carried out by Stuart *et al* (2017) which found that 3 out of 4 of the participants were unaware of generic drugs. [1]

One of the many roles of healthcare professionals within the primary healthcare system is educating clients about their medications, their functions and composition (whether original/brand name or generic). Therefore, the author opined that it is of utmost importance healthcare professionals should educate clients about their medication/drug regimen since Stuart *et al* (2015) demonstrated that innovator products that carries the same trade name (original drug created) were considered statistically different but had analogous biopharmaceutical effects. This research study emphasized that the same trade name does not necessarily indicate the pharmaceutical products are identical; principally they were produced by various manufacturers. [61] Hence the importance for the generics to be similar to the innovator product and must be evaluated in relation to an appropriate innovator.

- ASSOCIATIONS

Utilizing above bivariate analysis, it was found that an association existed between the overall satisfaction and the risk of non-adherence among respondents, (***Table 4 & Table 5a***). This association was similarly found in Bharmal *et al* (2009), however in a positive nature which indicated that as satisfaction of the respondents increased; particularly satisfaction with the effectiveness and convenience of medications; so, to do the chance of adherence. [40] Geitona *et al* (2007) further explored this relationship as low satisfaction among clients having an impact on drug adherence, however in this paper it was found that no statistically significant impact was found between the two variables when taking into account all the other statistically significant factors. [41]

Overall satisfaction had statistically significant associations with the effectiveness of generic medications, convenience, knowledge and risk of non-adherence, (***Table 4 , Table 5a and 5b***). These associations were all positive implying that as these factors increased so did the overall satisfaction experienced by the respondents. These findings were unsurprising as the overall goal of a respondent in taking medications was to treat an illness, therefore if their current medications were currently effective towards their chronic disease condition then their level of satisfaction would be affected by the results.

One of the greatest obstacles for respondents was the cost of medications. As well, the ready availability of generic medications and the ready access to plan and take their medications should have some effect on their level of satisfaction. Bertoldi *et al* (2005) and Dubina *et al* (2009) provided an assessment on how the knowledge of respondents on generic medications influenced their purchasing of medicines. [36,37] Using this study as a rough basis for which some elements were incorporated into the study instrument it was assumed that the relationship between knowledge and overall satisfaction were influenced by the cost for generic medications, chemical composition of generic medications and background of the creation of the generic medications ***(Appendix F, Table 8).*** The findings revealed that the relationship between knowledge and overall satisfaction was also influenced by knowledge of the medication names ***(Table 6b).***

- LINEAR REGRESSION

Generic medication factors that contributed to the overall satisfaction of respondents towards the management of their chronic diseases were the effectiveness and convenience of these generic drugs, (***Table 6a***). These findings strengthened the implication that the more effective and convenient a generic medication experienced by a respondent, then the higher their overall satisfaction, as these factors directly contribute to overall satisfaction, suggesting that physicians can look at these factors when prescribing

potential generic medications in order to provide their clients with the most satisfying experience in managing their chronic disease.

- ASSOCIATIONS

The risk of non-adherence was associated with a number of demographic and generic medications' factors including *age, employment, education level achieved, monthly income, effectiveness of medication, knowledge, attitudes* and *overall satisfaction*. These associations implied that the younger the respondent and the better their employment status, education level and monthly income, the less at risk they were in becoming non-adherent.

In relation to generic medications' factors, the more effective the medication, the more positive the respondents' attitude and the more knowledgeable the respondent, then the less likely the increased risk of non-adherence. These relationships are understandable given the reality associated with these factors as they relate to non-adherence. This study was similar to Bertoldi *et al* (2005) demographic profile, however in Bertoldi *et al* (2005) study the dependent variable was generic medication usage and not the risk of non-adherence. [36]

- LOGISTIC REGRESSION

The above logistic regression analysis provided a glimpse of all the factors that impacted the increased risk of generic medications' non-adherence among the sample, (***Table 7***). It suggested that persons were less likely to be at increased risk of non-adherence if they were employed or unemployed when compared to retirees. This indicated that the retired respondents were at a higher risk than others in the sample. This can be as a consequence of memory related issues when taking their medications.

The analysed research findings revealed that respondents who earned less than $3,000.00 were at increased risk of non-adherence compared to those who earned greater than $3,000.00, which suggested that the cost of generic medications may have affected their ability to purchase the drugs or even access them. However, if respondents had a negative attitude towards generic medications, then they were unlikely to be complaint, which was similar to the conclusion obtained by Hassali *et al* (2005). [30]

The author posited that individuals who were knowledgeable about their generic medications were twice as likely to be adherent and as a result were at a lower risk of non-adherent as they were aware of the benefits to their health that were being provided by these medications. This was further emphasised by Kendall *et al* (1991) where educating clients increased the level of acceptance and satisfaction, as persons were more motivated and confident in purchasing generic medications over brand name medicines. [32]

Notwithstanding the above limitation chapter, the author must make mention that some of the research findings were limited by the respondents' highest level of education achieved and monthly income. Therefore, the conclusive findings were skewed towards those with the lower education level and those with the lowest monthly income. However, the sampling method that was adopted to maintain objectivity and minimize and/or prevent research bias but prevented a generalization on the part of the research to reflect on behaviour factors outside the scope of this research paper. The minimum number of cases for a statistically significant value were met by the variables within these demographic characteristics allowing for confident statistical analysis. As a result, it is proposed that future papers related to generic medications for chronic diseases should cover all demographic characteristics as they are reflected by the national population.

CONCLUSION

The research sample population explored within this paper provided a diverse background, with a fairly-sized, female-driven demographic of individuals, both married and single, with primary school level education and monthly incomes of less than $3,000.00 among the majority of respondents. The employment status of the sample appeared fairly balance between employed, unemployed and retirees, with ages averaging 61 years old. Most of the sample population were fairly knowledgeable about their generic medications and provided an indifferent attitude towards these drugs within the North Central Regional Health Authority (NCRHA).

Overall, the researched sample population responded positively to generic medications that treat their chronic-disease conditions and indicated a level of acceptability in using these medications. On average respondents had a moderate level of satisfaction with their generic medication which was influenced by the convenience and effectiveness of these medications similar to Figueiras *et al* (2008) study. Satisfaction by respondents was driven by perception of cost, ingredients in the medications and background of the medications. This background alluded to the clinical test and other forms of research that a respondent may be aware of that was carried out to produce their medication. If generic medications were cheaper, made with the same ingredients as the original/brand name counterpart and did not undergo clinical trials, then respondents were likely to be satisfied with their medications.

The risk of non-adherence among respondents indicated that approximately half of the sample population were at a higher risk of non-adherence. Moreover, the factors associated with risk of non-adherence included *respondents' age, employment status, education level achieved, monthly income* along with *generic drug related factors, knowledge and attitudes* of generic medications. This risk of non-adherence was also influenced by a participants' *employment, education level* and *monthly income, knowledge and attitudes of generic medications*, which would suggest that the better educated and financially stable a person was coupled with their outlook of their diagnosis, the less likely they were to be at increased risk of non-adherence.

Therefore, the author has recommended that future research studies can reference these research findings and should explore the level at which generic medications manage chronic diseases compared to brand-named medications. Moreover, that research study should focus on the overall effect both treatment options provide patients in order to determine if generic medications are managing patients' health effectively and providing to the health needs of those patients. Thus, combing this research study with additional comprehensive research are potentially capable of informing healthcare professionals on which

generic medications have the most impact in treating their chronic disease conditions and can provide an equitable platform for clients in their decision making when it comes to using medications. Notwithstanding, further researching the identified factors herein that can have an impact with overall satisfaction and increased risk of non-adherence as indicators to measure the difference those impacts may have towards generic medications and brand-named drugs; thereby evaluating those differences.

Nonetheless, the author was able to achieve the aims and objectives of this research as outlined above and it is hoped that these research findings would have a significant and positive impact on healthcare education in promotion and advancing quality healthcare services within the primary healthcare system; especially Trinidad and Tobago.

REFERENCES

1. Stuart A, Gupta M, Sealy P. Patients' Perception of Generic Drugs at Health Institutions in Trinidad and Tobago. Journal of Young Pharmacists. 2017;9(3):362-366.

2. Ganther J, Kreling D. Consumer Perceptions of Risk and Required Cost Savings for Generic Prescription Drugs. Journal of the American Pharmaceutical Association (1996). 2000;40(3):378-383.

3. World Health Organization, 2004. Generic drugs. Department of Trade, foreign policy, diplomacy and health of WHO. Geneva: WHO press. Available from: http://www.int/trade/glossary/story034/en/. [Last accessed on 10 April,2014].

4. Zaverbhai K, Dilipkumar K, Kalpan D, Kiran D. Knowledge, Attitude and Practice of Resident Doctors for use of Generic Medicines at a Tertiary care Hospital. Journal of Young Pharmacists. 2017;9(2):263-266.

5. Swain T, Giri P. Generic Medicines: Old wine in new bottle? Journal of Young Pharmacists. 2015;7(3):143-144.

6. Trinidad STEPS SURVEY- FINAL DRAFT _ Pan American Steps Chronic Non-Communicable Disease Risk Survey Final Report [Internet]. Ministry of Health Government of Trinidad and Tobago; 2018 [cited 11 October 2018]. Available from: http://www.who.int/ncds/surveillance/steps/TrinidadAndTobago_2011_STEPS_Report.pdf

7. Hassali MA, Alrasheedy AA, McLachlan A et al. The experiences of implementing generic medicine policy in eight countries: A review and recommendations for a successful promotion of generic medicine use. Saudi Pharm J. 2014; 22:491-503. https://doi.org/10.1016/j.jsps.2013.12.017 PMid:25561861 PMCid:PMC4281627.

8. What are generic drugs? Fda.gov. (2018). *Generic Drug Facts*. [online] Available at: https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm [Accessed 2 Oct. 2018].

9. FDA. Therapeutic Equivalence of Generic Drugs: Letter to Health Practitioners. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm073182.htm. Accessed August 10, 2017.

10. Verbeeck R. Bioequivalence, Therapeutic Equivalence And Generic Drugs. Acta Clinica Belgica [Internet]. 2009 [Cited 2 October 2018];64(5):379-383. Available From: Http://Bioequivalence, Therapeutic Equivalence And Generic Drugs

11. Zarowitz B. The Generic Imperative. Geriatric Nursing. 2008;29(4):223-226.

12. Lewek, MD P, Kardas, MD, PhD P. Generic drugs: The benefits and risks of making the switch [Internet]. 1st ed. Poland: J Fam Pract.; 2010 [cited 2 October 2018].

13. Measuring the return from pharmaceutical innovation 2012 Is R&D earning its investment? [Internet]. The Deloitte Centre for Health Solutions; 2012 [cited 15 October 2018]. Available

from: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-measuring-the-return-from-pharma-innovation-2012.pdf

14. Johnston A, Stafylas P, Stergiou G. Effectiveness, safety and cost of drug substitution in hypertension. British Journal of Clinical Pharmacology. 2010;70(3):320-334.

15. Nakai K, Fujita M, Ogata H. International harmonization of bioequivalence studies and issues shared in common. Yakugaku Zasshi. 2000;120:1193–1200.

16. Crawford P, Feely M, Guberman A, et al. Are there potential problems with generic substitution of antiepileptic drugs? A review of issues. Seizure. 2006;15:165–176.

17. Borgheini G. The bioequivalence and therapeutic efficacy of generic versus brand-name psychoactive drugs. Clin Ther. 2003;25:1578–1592

18. Meyer M C (2001) United States Food and Drug Administration requirements for approval of generic drug products. J Clin Psychiatry 62 Suppl 5: 4-9

19. Rosenbaum D H, Rowan A J, Tuchman L, French J A (1994) Comparative bioavailability of a generic phenytoin and Dilantin. Epilepsia 35: 656-600

20. The Ministry of Health - Trinidad and Tobago [Internet]. Health.gov.tt. 2019 [cited 30 March 2019]. Available from: http://www.health.gov.tt/sitepages/default.aspx?id=93

21. Shikiar R, Rentz A. Satisfaction with Medication: An Overview of Conceptual, Methodologic, and Regulatory Issues. Value in Health. 2004;7(2):204-215.

22. Jasen M, Rush B, Epping-Jordan J, Lalji M, Hildebrand J, Monterio M. Client Satisfaction Evaluations [Internet]. World health organization; [cited 30 March 2019]. Available from: http://whqlibdoc.who.int/hq/2000/WHO_MSD_MSB_00.2g.pdf;

23. Joseph C, Nichols S. Patient satisfaction and quality of life among persons attending chronic disease clinics in South Trinidad, West Indies. West Indian Medical Journal. 2007;56(2).

24. Aharony L, Strasser S. Patient satisfaction: what we know about and what we still need to explore. Med Care Rev 1993; 50: 49–79.

25. MDG 8: Develop a Global Partnership for Development | Sustainable Development Goals | Food and Agriculture Organization of the United Nations [Internet]. Fao.org. [cited 30 March 2019]. Available from: http://www.fao.org/sustainable-development-goals/mdg/goal-8/en/

26. Thomas R, Vitry A. Consumers perception of generic medicines in community pharmacies in Malaysia [Internet]. Australia: Southern Med Review; 2008 [cited 27 March 2019]. Available from: https://www.researchgate.net/scientific-contributions/2009423516_Raynu_Thomas

27. Dunne S, Shannon B, Dunne C, Cullen W. A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study. BMC Pharmacology and Toxicology. 2013;14(1).

28. Haas J, Phillips K, Gerstenberger E, Seger A. Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997–2000. Annals of Internal Medicine. 2005;142(11):891.

29. Lambert Z, Doering P, Goldstein E, McCormick W. Predispositions Toward Generic Drug Acceptance. Journal of Consumer Research. 1980;7(1):14.

30. Hassali MA *et al.* Generic medicines: perceptions of consumers in Melbourne Australia. *Int J Pharm Pract* 2005; 13(4): 257–264.

31. Valles JA *et al.* A prospective multicenter study of the effect of patient education on acceptability of generic prescribing in general practice. *Health Policy* 2003; 65(3): 269–275.

32. Kendall KW *et al.* Consumer response to generic/chemically equivalent drugs. *J Public Policy Mark* 1991; 10(2): 182–201.

33. Heikkila R. *et al.* Customers' and physicians' opinions of and experiences with generic substitution during the first year in Finland. *Health Policy* 2007; 82(3): 366–374.

34. Leppänen P. CUSTOMER SATISFACTION SURVEY, RESULT ANALYSIS AND UTILIZATION IN A GLOBAL FORESTRY COMPANY [Internet]. 2016 [cited 5 December 2018]. Available from: https://www.theseus.fi/bitstream/handle/10024/117847/Leppanen_Pauliina.pdf?sequence=1

35. Figueiras JM *et al.* People's views on the level of agreement of generic medicines for different illnesses. *Pharm World Sci* 2008; 30: 590–594.

36. Bertoldi AD *et al.* Generic drugs in Brazil: known by many, used by few. *Cadernos de saude publica/Ministerio da Saude, Fundacao Oswaldo Cruz, Escola Nacional de Saude Publica* 2005; 21(6): 1808–1815.

37. Dubina M, O'Neill J L, Feldman S R. Effect of patient satisfaction on outcomes of care. Expert Rev. Pharmacoeconomics Outcome Res. 9(5), 393-395 (2009).

38. . Katusiime B, Corlett S, Reeve J, Krska J. Measuring medicine-related experiences from the patient perspective: a systematic review. Patient Related Outcome Measures. 2016;Volume 7:157-171.

39. T M, G S, V.V S, E S, K I, T U. DRUG COMPLIANCE AND ADHERENCE TO TREATMENT. Journal of Evolution of Medical and Dental Sciences. 2012;1(3):142-159.

40. Bharmal M, Payne K, Atkinson M, Desrosiers M, Morisky D, Gemmen E. Validation of an abbreviated Treatment Satisfaction Questionnaire for Medication (TSQM-9) among patients on antihypertensive medications. Health and Quality of Life Outcomes. 2009;7(1).

41. Geitona M, Kyriopoulos J, Zavras D, Theodoratou T, Alexopoulos E. Medication use and patient satisfaction: a population-based survey. Family Practice. 2008;25(5):362-369.

42. Brod M, Cobden D, Lammert M, Bushnell D, Raskin P. Examining correlates of treatment satisfaction for injectable insulin in type 2 diabetes: lessons learned from a clinical trial comparing biphasic and basal analogues. Health and Quality of Life Outcomes. 2007;5(1).

43. Testa M, Simonson D. Satisfaction and Quality of Life with Premeal Inhaled Versus Injected Insulin in Adolescents and Adults with Type 1 Diabetes. Diabetes Care. 2007;30(6):1399-1405.

44. Singh N, Squeir C, Sivek C, Wagener M, Nguyen MH, Yu VL. Determinants of compliance with antiretroviral therapy in patients with human immunodeficiency virus: prospective assessment with implications for enhancing compliance. AIDS Care. 1996;8:261.

45. Kalogianni, A., 2011. Factors affect in patient adherence to medication regimen. *Factors affect in patient adherence to medication regimen*, 5(3), pp.157-158.

46. Bonnick S, Silverman S, Tanner S, Martens M, Bachmann G, Kohles J et al. Patient Satisfaction in Postmenopausal Women Treated with a Weekly Bisphosphonate Transitioned to Once-Monthly Ibandronate. Journal of Women's Health. 2009;18(7):935-943.

47. Kim J, Combs K, Downs J, Tillman F. Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

48. . Auta A, Bala E, Shalkur D. Generic Medicine Substitution: A Cross-Sectional Survey of the Perception of Pharmacists in North-Central, Nigeria. Medical Principles and Practice. 2014;23(1):53-58.

49. Håkonsen H, Eilertsen M, Borge H, Toverud E. Generic substitution: additional challenge for adherence in hypertensive patients?. Current Medical Research and Opinion. 2009;25(10):2515-2521.

50. Wijk B, Klungel O, Heerdink E, Boer A. Generic Substitution of Antihypertensive Drugs: Does it Affect Adherence?. Annals of Pharmacotherapy. 2006;40(1):15-20.

51. Ghauri P, Grønhaug K. Research methods in business studies. 3rd ed. Harlow, UK: Financial Times Prentice Hall; 2005.

52. Healthcare in Trinidad and Tobago [Internet]. En.m.wikipedia.org. 2018 [cited 5 November 2018]. Available from: https://en.m.wikipedia.org/wiki/Healthcare_in_Trinidad_and_Tobago

53. Mann C. Observational research methods. Research design II: cohort, cross sectional, and case-control studies. Emergency Medicine Journal [Internet]. 2003 [cited 1 October 2018];20(1):54-60. Available from: https://emj.bmj.com/content/20/1/54

54. Bharmal M, Payne K, Atkinson M, Desrosiers M, Morisky D, Gemmen E. Validation of an abbreviated Treatment Satisfaction Questionnaire for Medication (TSQM-9) among patients on antihypertensive medications. Health and Quality of Life Outcomes. 2009;7(1).

55. Delestras S, Roustit M, Bedouch P, Minoves M, Dobremez V, Mazet R et al. Comparison between Two Generic Questionnaires to Assess Satisfaction with Medication in Chronic Diseases. PLoS ONE. 2013;8(2):e56247

56. . Ruiz M, Pardo A, Rejas J, Soto J, Villasante F, Aranguren J. Development and Validation of the "Treatment Satisfaction with Medicines Questionnaire" (SATMED-Q)©. Value in Health. 2008;11(5):913-926.

57. Lavsa S, Holzworth A, Ansani N. Selection of a validated scale for measuring medication adherence. Journal of the American Pharmacists Association. 2011;51(1):90-94.

58. Lam, A., 2011. Practice Innovations: Delivering Medication Therapy Management Services via Videoconference Interviews. *The Consultant Pharmacist*, 26(10), pp.764-774.

59. Shelton, P., Mozingo, D., Avissar, P., Karg, M., Charboneau, A. and Rich, W., 2012. Measuring Adherence in a Community-Based Elderly Population. *The Consultant Pharmacist*, 27(11), pp.771-781.

60. World Medical Association (WMA). Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Jahrbuch für Wissenschaft und Ethik [Internet]. 2009 [cited 30 November 2018];14(1). Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

61. Stuart A, Clement Y, Sealy P, Löbenberg R, Montane-Jaime L, Maharaj R et al. Comparing the Dissolution Profiles of Seven Metformin Formulations in Simulated Intestinal Fluid. Dissolution Technologies. 2015;22(1):17-21.

APPENDICES

APPENDIX A: Approval Letters

THE UNIVERSITY OF THE WEST INDIES
ST AUGUSTINE, TRINIDAD AND TOBAGO, WEST INDIES
CAMPUS RESEARCH ETHICS COMMITTEE
TEL.: (1-868) 662-2002 ext. 82755 E-mail: campusethics@sta.uwi.edu

September 10 2019

Dr. Shastri Motilal (Dr. Sarah Sampath)
Department of paraclinical sciences;

Faculty of medical sciences;

EWMSC, Champ Fleurs
Email: shastri.motilal@sta.uwi.edu

Dear Dr. Shastri Motilal,

Ref: CREC-SA.0007/08/2019

Title: A cross-sectional study: Evaluation of clients' satisfaction with generic medications in management of their chronic-diseased conditions in NCRHA- Primary Healthcare Institutions

I am pleased to advise that your application for research on the above captioned topic has been approved on behalf of Campus Research Ethics Committee, St. Augustine.

Sincerely,

Surendra Arjoon (Prof.)
Chairman
Ethics Committee

THE UNIVERSITY OF THE WEST INDIES
ST AUGUSTINE, TRINIDAD AND TOBAGO, WEST INDIES
CAMPUS RESEARCH ETHICS COMMITTEE
TEL.: (1-868) 662-2002 ext. 82755 E-mail: campusethics@sta.uwi.edu

CONSENT TO PARTICIPATE IN RESEARCH

Complete Protocol Title: A cross-sectional study: Evaluation of clients' satisfaction with generic medications in management of their chronic-diseased conditions in NCRHA- Primary Healthcare Institutions

Principal Investigator: Dr. Shastri Motilal

Co Investigator(s): Dr. Sarah Sampath

Research Sites: San Rafael health centre; La Horquetta health centre and Arima health centre

Sponsors: None

Why is this research being done?

The main aim of this research study is to perfrom an investigative study to determine the satisfaction level of primary health care clients in the use of prescribed generic medications in the management of their chronic diseases. Additionally, the study would also be able to determine the proportion of clients who are compliant with their chronic diseased medications.

What is the duration of taking part in the study (for each subject)?

The questionnaire shall comprise of concise and non-problematic questions that each participant can complete within 20 minutes. Participation is voluntary and enrolment would be done via simple ramdomization. Each participant would be fully informed of what the study entails and its aims and objectives prior to enrolment in the study once they are in full agreement and fully understood the aims and objectives.

What will happen to me?

No harm would be incurred to you the participant

What is in in for me?

Participating in this study is free and voluntary. There are no financial rewards/payments, gifts or any type of inducements in partcipating in the study. The researcher would be greatly appreciative and sincerely values your time and nergy in completing the survey honestly. The information provided by you would be contributing to a better primary health care system.

What will happen if I drop out of the study early?

One is free to withdraw at any time during the study and there would be no repercussions.

What are my responsibilities if I join and what about confidentiality?

Confidentiality would be maintained at all times during and even after completion of the study. Your main responsibility would be to answer the questions honestly and free from bias.

What if I get hurt in the study?

No physical and/or psychological harm would happen to you

CONSENT

I have read and understood this explanation. The researcher has also explained the study to me. I have had a chance to ask questions and have them answered to my satisfaction. I agree to take part in this study. I have not been forced or made to feel like I had to take part.

I have read the attached experimental Subject's Rights, which contain some important information about research studies. I have also read the Authorisation to use my Private Health Information. **I must sign this Consent Form, the Experimental Subject's Rights and the Authorisation to use my Private Health Information. I will be given a signed copy of each to keep**.

Print Name of Subject

_____

Signature of Subject Date

_____ _____

Signature of Person conducting the informed consent discussion Date

_____ _____

Role of person named above in the research project

_____

Signature of Second Witness Date

_____ _____

By Chairman:

This document was approved by Campus Ethics Committee on:
September 10 2019
This document expires on:
2019-12-13

EXPERIMENTAL SUBJECT'S RIGHTS

If I am asked to consent to participate as a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to:

1. Learn the nature and purpose of the experiment (also called "study" or "clinical trial").
2. Receive an explanation of the procedures to be followed in the study, and any drug or device used.
3. Receive a description of any discomforts and risks that I could experience from the study.
4. Receive an explanation of any benefits I might expect form the study.
5. Learn about the risks and benefits of any other available procedures, drugs or devices that might be helpful to me.
6. Learn what medical treatment will be made available to me if I should be injured as a result of this study.
7. Ask any questions about the study or the procedures involved.
8. Quit the study at any time, and my decision will not be used as an excuse to withhold necessary medical treatment.
9. Receive a copy of the signed and dated consent form.
10. Decide to consent or not to consent to a study without feeling forced or obligated.

If I have questions about a research study, I can call the contact person listed on the consent form. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Principal Investigator, The University of the West Indies at: shastri.motilal@sta.uwi.edu, 710-9545.

By signing this document, I agree that I have ready and received a copy of this document.

Signature of Subject or Legal Representative _____ Date _____

REQUEST FOR PERMISSION TO USE AN INDIVIDUAL'S PRIVATE HEALTH INFORMATION

Name of Study: A cross-sectional study: Evaluation of clients' satisfaction with generic medications in management of their chronic-diseased conditions in NCRHA- Primary Healthcare Institutions

Investigators: Dr. Shastri Motilal, Dr. Sarah Sampath

What is private health information?

Private health information is any information that can be traced back to you. We need your permission to use your private health information in this research study. The type of private health information that will be used and shared for this study includes:

- Your past and present physical and mental health information
- Information that can be used to contact you
- Results of your medical tests and DNA
- Questionnaires and information on your drug/alcohol usage and that of your family.

Who else will see my information?

The Principal Investigator, Dr. Shastri Motilal, and myself, Dr. Sarah Sampath. As well, the trained healthcare professionals who would provide assistance in performing the survey to you the participant.

How long will the investigators use and share my information?

Your information would be used for a minimum of 5 years. The intent would be to publish the research findings and you the participant can request a copy of the published research findings when it is made available.

What if I change my mind about sharing my research information?

Participation is fully voluntary and you can withdraw from this study at any time. There would be no repercussions if you wish for your research information to not be shared.

Do I have the right to see and copy my research information?

Yes you have the right to see and copy your research information.

If you agree to share your information, you should sign this form below. You will receive a copy of this form.

I agree to share my information as described in this form

Print Name	Signature	Date

If you have questions or concerns about your privacy and the use of your personal medical information, please contact the investigator at the telephone number listed in the consent form.

Letter to CEO NCRHA requesting approval for research to be done

01th October 2019

Mr. Davlin Thomas

Chief Executive Officer

North Central Regional Health Authority

EWMSC

Champs Fleurs

Re: Request for approval to conduct research " A cross-sectional study: Evaluation of clients' satisfaction with generic medications in management of their chronic diseased conditions in NCRHA- Primary Healthcare Institutions"

Dear Mr. Thomas,

I am writing in the capacity as a postgraduate student currently enrolled in the DM Family Medicine program with the University of the West Indies, Faculty of Medical Sciences, St. Augustine Campus.

I have received ethics approval from the UWI for the above-mentioned research. The proposed research study would be under the supervision of Dr. Shastri Motilal, one of the lecturers in the Family Medicine program.

The proposed research study would entail distributing questionnaires to randomly chosen chronic diseased clients from the San Rafael Health Centre, La Horquetta Health Centre and the Arima Health Centre; the chronic disease clinics of these three health centres; regarding their satisfaction with the use of generic medications in the management of their chronic diseased conditions. The questionnaires would be completed in the clinic setting and the questionnaires would be interviewer administered.

I wish to inform you that privacy and confidentiality would be maintained at all times during and even after completion of the proposed research study.

Please find attached:

The Full Research Proposal

Consent form for the clients/patients

Questionnaire

UWI Ethics committee approval letter

I, the co-investigator, agree to submit a copy of the final paper upon completion of this research study. If there are any concerns, please feel free to contact me.

I thank you in advance for your consideration of my request to conduct research at clinics under the NCRHA.

Respectfully Submitted

Dr. Sarah Sampath

M.B.,B.S., PG Dip Family Medicine, Masters in Family Medicine

Primary Care Physician 1

Tel: 740-1962

Email: drsampath2005@yahoo.com

Approval letter from NCRHA for study

NORTH CENTRAL REGIONAL HEALTH AUTHORITY

OFFICE OF THE CHIEF EXECUTIVE OFFICER
3rd Floor, Building 39, Eric Williams Medical Sciences Complex, Uriah Butler Highway,
Champs Fleurs PBX: (868)-225-4673 Ext: 2490 / 3089 / 5091 D.L: (868)-662-5579
Fax: (868)-663-0671

October 21st, 2019

Dr. Sarah Sampath
Student (UWI)
EWMSC
Mt. Hope.

Dear Dr. Sampath,

Approval to conduct a research project within the NCRHA

Reference is made to the subject at caption.

Please be informed that approval has been granted for the research titled – "**Across-sectional study: Evaluation of clients' satisfaction with generic medications in management of their chronic-diseased *conditions* in NCRHA – Primary Healthcare Institutions.**" The commencement of this research indicates that you have understood and accepted the responsibility of maintaining the confidentiality of all data and information collected and processed.

The NCRHA wishes you every success in this undertaking, and looks forward to receiving a **SOFT** copy of your Project Report within two (2) weeks of completion.

Sincerely,

Davlin Thomas
Chief Executive Officer

x.c: *Public Health Observatory, NCRHA*
Dr. Rodney Ramroop – Director of Health, NCRHA
Dr. Abdul Hamid – General Manager, Primary Healthcare Services, NCRHA
Ms. Claudette Fraser-Udika – General Manager, Nursing Services, NCRHA
Ms. Calistra Thomas – Primary Care Nurse Manager, AHF
Dr. Keisha Gangaram – PCP II, AHF

Appendix B: The Survey

A Cross-Sectional Study: Evaluation of Clients' Satisfaction with Generic Medications in Management of their Chronic-Disease Conditions in NCRHA-Primary Healthcare Institutions.

SURVEY QUESTIONNAIRE

The principal researcher kindly requests you, the participant, to complete this survey to the best of your ability. Participation is completely voluntary and there shall be no penalty or negative effects if you choose to withdraw before completing this questionnaire. A research assistant would be administering the survey to you. The research assistant is a qualified healthcare professional who was trained in delivering the survey. Please be assured that the information provided shall be kept private and confidential by the principal researcher and/or research assistant. On behalf of the principal researcher, thank you for your valued time and energy for your participation.

DEFINITIONS:

An original/brand name medicine is one that is discovered, developed and marketed by a pharmaceutical company, for example, Glucophage in treating Diabetes Mellitus.

A generic medicine is manufactured to be as a substitute to the original/brand name medicine; they are made to be similar to their original/brand name medicine; for example, the generic for Glucophage is Metformin which is well is used in the treatment of Diabetes Mellitus.

SECTION A

DEMOGRAPHIC DATA

Please tick the appropriate box for each of the following questions:

1. Gender: Male **[ ]** Female **[ ]**

2. Please state your age:

3. Marital Status: Single **[ ]** Married/Engaged **[ ]** Divorced **[ ]**

Common-law **[ ]**

4. Employment Status: Employed **[ ]** Unemployed **[ ]** Retiree **[ ]**

5. Highest Level of Schooling Achieved: Primary School **[ ]**

Secondary School **[ ]** Tertiary Level **[ ]** Vocation/ Trade **[ ]**

6. Monthly Income ($): < $3000.00 [ ] $3000.00- $5000.00 [ ]

$5000.00- $7000.00 [ ] >$7000.00 [ ]

7. Please specify which chronic-diseased condition (s) you have. *Tick all the appropriate boxes:*

Diabetes Mellitus **[ ]** Hypertension **[ ]** Cardiovascular Disease/ Heart **[ ]**

Cerebrovascular Disease/ Stroke **[ ]** Dyslipidaemia/Cholesterol **[ ]**
Asthma **[ ]**

Others: Please Specify: _____

8. How long have you been diagnosed with your chronic disease condition/s? Please state the number of years: _____

9. How long have you been receiving treatment for your chronic disease condition/s? Please state the number of years: _____

SECTION B

KNOWLEDGE ABOUT GENERIC MEDICINES

This section involves asking simple questions assessing your knowledge about generic medications. The responses for each question range from Strongly Agree to Strongly Disagree. Please circle the most appropriate response for each of the questions being asked. The last question in this section would ask for you to choose the most appropriate response and to list your reasons for your chosen response.

1. Generic medicines contain the same ingredient as the original/brand name medications.

Strongly Agree Agree Neutral Disagree Strongly Disagree

2. Generic medicines are usually interchangeable with the original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

3. Generic medicines need to undergo clinical testing just like original/brand named medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

4. Generic medicines are intended to be used the same as original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

5. Generic medicines are important for reducing overall health cost.

Strongly Agree Agree Neutral Disagree Strongly Disagree

6. Generic medicines provide quality care at an affordable cost.

Strongly Agree Agree Neutral Disagree Strongly Disagree

7. Generic medicines are cheaper as compared to original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

8. Generic medicines produce similar adverse reactions as original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

9. Have you switched from using generic medications to original/brand name medications for treating your chronic disease condition/s?

YES[ ] NO[ ] NOT SURE[ ]

Please give your reasons for your chosen response:

_____
_____
_____

SECTION C

ATTITUDES ABOUT GENERIC MEDICINES

This section involves asking simple questions assessing your attitudes about generic medications. The responses for each question range from Strongly Agree to Strongly Disagree. Please circle the most appropriate response for each of the questions being asked.

1. Generic medicines are not as safe as the original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

2. Generic medicines are not as effective as original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

3. Generic medicines take longer to act in the body.

Strongly Agree Agree Neutral Disagree Strongly Disagree

4. Generic medicines cost less because they are inferior to the original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

5. Generic medicines have doubtful efficacy in chronic diseases.

Strongly Agree Agree Neutral Disagree Strongly Disagree

6. Generic medicines take a similar time to act in the body as the original/brand name medicines.

Strongly Agree Agree Neutral Disagree Strongly Disagree

SECTION D

TREATMENT SATISFACTION QUESTIONNAIRE FOR MEDICATION/S

This section addresses the client's level of treatment satisfaction with their medications. Please tick the most appropriate response.

1. How satisfied or dissatisfied are you with the ability of the medication/s to prevent or treat your condition?

[ ]1. Extremely Dissatisfied [ ]2. Very Dissatisfied [ ]3. Dissatisfied

[ ]4. Somewhat Satisfied [ ]5. Satisfied [ ]6. Very Satisfied

[ ]7. Extremely Satisfied

2. How satisfied or dissatisfied are you with the way the medication/s relieves your symptoms?

[ ]1. Extremely Dissatisfied [ ]2. Very Dissatisfied [ ]3. Dissatisfied

[ ]4. Somewhat Satisfied [ ]5. Satisfied [ ]6. Very Satisfied

[ ]7. Extremely Satisfied

3. How satisfied or dissatisfied are you with the amount of time it takes the medication/s to start working?

[ ]1. Extremely Dissatisfied [ ]2. Very Dissatisfied [ ]3. Dissatisfied

[ ]4. Somewhat Satisfied [ ]5. Satisfied [ ]6. Very Satisfied

[ ]7. Extremely Satisfied

4. As a result of taking this medication/s, do you currently experience any side effects at all?

YES **[ ]** NO **[ ]**

If YES go to #5.

If NO go to #9.

5. How bothersome are the side effects of the medication/s you take to treat your condition?

[ ]1. Extremely Bothersome [ ]2. Very Bothersome

[ ]3. Somewhat Bothersome [ ]4. A Little Bothersome

[ ]5. Not at All Bothersome

6. To what extent do the side effects interfere with your physical health and ability to function (strength, energy levels)?

[ ]1. A Great Deal [ ] 2. Quite a Bit [ ]3. Somewhat

[ ]4. Minimally [ ]5. Not at All

7. To what extent do the side effects interfere with your mental function (ability to think clearly, stay awake)?

[ ]1. A Great Deal [ ] 2. Quite a Bit [ ]3. Somewhat

[ ]4. Minimally [ ]5. Not at All

8. To what degree have medication side effects affected your overall satisfaction with the medication/s?

[ ]1. A Great Deal [ ] 2. Quite a Bit [ ]3. Somewhat

[ ]4. Minimally [ ]5. Not at All

9. How easy or difficult is it to use the medication/s in its current form?

[ ]1. Extremely Difficult [ ]2. Very Difficult [ ]3. Difficult

[ ]4. Somewhat Easy [ ]5. Easy [ ]6. Very Easy

[ ]7. Extremely Easy

10. How easy or difficult is it to plan when you will use the medication/s each time?

[ ]1. Extremely Difficult [ ]2. Very Difficult [ ]3. Difficult

[ ]4. Somewhat Easy [ ]5. Easy [ ]6. Very Easy

[ ]7. Extremely Easy

11. How convenient or inconvenient is it to take the medication/s as instructed?

[ ]1. Extremely Inconvenient [ ]2. Very Inconvenient [ ]3. Inconvenient

[ ]4. Somewhat Convenient [ ]5. Convenient [ ]6. Very Convenient

[ ]7. Extremely Convenient

12. Overall, how confident are you that taking these medication/s is/are a good thing for you?

[ ]1. Not at All Confident [ ]2. A Little Confident

[ ]3. Somewhat Confident [ ]4. Very Confident

[ ]5. Extremely Confident

13. How certain are you that the good things about your medication/s outweigh the bad things?

[ ]1. Not at All Certain [ ]2. A Little Certain

[ ]3. Somewhat Certain [ ]4. Very Certain [ ]5. Extremely Certain

14. Taking all things into account, how satisfied or dissatisfied are you with the medication/s?

[ ]1. Extremely Dissatisfied [ ]2. Very Dissatisfied [ ]3. Dissatisfied

[ ]4. Somewhat Satisfied [ ]5. Satisfied [ ]6. Very Satisfied

[ ]7. Extremely Satisfied

SECTION E

COMPLIANCE WITH YOUR MEDICATION/S

This section addresses questions pertaining to your compliance with your medications. Please tick the most appropriate response

1. Do you know what each of your medications is for?

[ ]YES [ ]NO [ ]DO NOT KNOW

2. Do you ever have trouble remembering when to take your medications?

[ ]YES [ ]NO [ ]DO NOT KNOW

3. Do you ever not take medications because you feel you do not need it?

[ ]YES [ ]NO [ ]DO NOT KNOW

4. Do you ever think that any of your medications are not helping you?

[ ]YES [ ]NO [ ]DO NOT KNOW

5. Do you have any physical problems that keep you from taking your medications as prescribed?

[ ]YES [ ]NO [ ]DO NOT KNOW

6. Do you think any of your medicines are causing a side effect?

[ ]YES [ ]NO [ ]DO NOT KNOW

7. Do you know the names of all of your medications?

[ ]YES [ ]NO [ ]DO NOT KNOW

8. Do you think that you need all of your medications?

[ ]YES [ ]NO [ ]DO NOT KNOW

9. In the past 6 months, have you missed getting a refill or a new prescription filled on time?

[ ]YES [ ]NO [ ]DO NOT KNOW

10. How often do you miss taking a dose of medication?

[ ]NEVER [ ] 1-2 TIMES/MONTH

[ ]ONE TIME A WEEK [ ]2 OR MORE TIMES A WEEK

11. Have you forgotten to take any of your medications within the past week?

[ ]YES [ ]NO

If YES, which one and how frequent? _____

What are some of the reasons you forget to take your medications?

_____

12. Is the cost of your medications a concern to you?

[ ]YES [ ]NO

END OF THE SURVEY

THANK YOU FOR YOUR PARTICIPATION AND VALUED CONTRIBUTION

APPENDIX C

Telephone Conversation with Client

Hi good day.

Can I speak to (name of client)?

I am Dr. Sampath and I am one of the doctors working at the Arima Health Facility, namely San Rafael Health Centre.

I am presently doing a survey and I randomly selected your name from the chronic disease register book located at the health centre you are attending.

I am enrolled in postgraduate studies in Family Medicine and I have a survey to do whereby I am evaluating clients' satisfaction with generic medications in the management of their chronic disease conditions.

Generic medications were created to be used as substitutes to the original/brand name medicines, such as Glucophage is the original drug for treating diabetes and Metformin is the generic version to it.

The survey wouldn't take more than 20 minutes to complete and either I or one of my colleagues would be assisting you in completing the survey.

Your participation is voluntary and i can assure you that utmost confidentiality would be maintained at all times.

If you agree to partake in the survey we can organise a suitable time for you to visit your health centre for the survey to be administered. Your participation would be of great assistance to me in completing my studies and the information obtained would be a great asset in enhancing the management of chronic disease conditions in our community.

I thank you for your time and co-operation.

APPENDIX D

PROTOCOL FOR DATA COLLECTION

1. Introduce and welcome client.

2. Direct client to the designated private area of the clinic for the survey to be administered.

3. Explain the purpose of the study using the participant information sheet.

4. Outline the aims and objectives of the study to the client.

5. Answer any concerns/queries from the client.

6. Review client's file and their medications once again.

7. Obtain voluntary, informed written consent from the client.

8. Administer the survey, complete one section before moving onto the next section. Use glucophage/metformin as the standard example when asking the questions for clarification.

9. Once survey completed thank client for his/her valued time and co-operation.

10. Store completed survey in the fire-proof cabinet.

11. Escort client to the health centre's exit.

APPENDIX E: Scoring Algorithms for the Validated Tools Used

MEDICATION ADHERENCE QUESTIONNAIRE AND SCORING ALGORITHM

The questionnaire consists of 12 questions with binary answering choices: Yes or No. The point-scoring method is listed in the table below. Patients are considered to be at risk for nonadherence when total point scored is 2 or higher.

Question	Yes/No/ Do not know	Score
1. Do you know what each of your medications is for?	No	1
2. Do you ever have trouble remembering when to take your medications?	Yes	1
3. Do you ever not take a medication because you feel you do not need it?	Yes	1
4. Do you ever think that any of your medications is not helping you?	Yes (if at least one is not helping)	1
5. Do you have any physical problems that keep you from taking your medications as prescribed?	Yes	1
6. Do you think any of your medicine is causing a side effect?	Yes	1
7. Do you know the names of all of your medications?	No	1
8. Do you think that you need all of your medications?	No	1
9. In the past 6 months, have you missed getting a refill or new prescription filled on time?	Yes	1
10. How often do you miss taking a dose of medication? 4 choices: a) never b) 1-2 times/month 3) one time a week 4) 2 or more times a week	One time a week or 2 or more times a week	1
11. Have you forgotten to take any of your medications within the past week? (If so, which one and how frequent?) (What are some of the reasons you forget to take your medicines?)	Yes	1
12. Is cost of your medication a concern to you?	Yes	1
	Total points	

TREATMENT SATISFACTION QUESTIONNAIRE AND SCORING ALGORITHM

1. How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?
   - ☐1 Extremely Dissatisfied
   - ☐2 Very Dissatisfied
   - ☐3 Dissatisfied
   - ☐4 Somewhat Satisfied
   - ☐5 Satisfied
   - ☐6 Very Satisfied
   - ☐7 Extremely Satisfied
2. How satisfied or dissatisfied are you with the way the medication relieves your symptoms?
   - ☐1 Extremely Dissatisfied
   - ☐2 Very Dissatisfied
   - ☐3 Dissatisfied
   - ☐4 Somewhat Satisfied
   - ☐5 Satisfied

☐6 Very Satisfied
☐7 Extremely Satisfied

3. How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?
   ☐1 Extremely Dissatisfied
   ☐2 Very Dissatisfied
   ☐3 Dissatisfied
   ☐4 Somewhat Satisfied
   ☐5 Satisfied
   ☐6 Very Satisfied
   ☐7 Extremely Satisfied
4. As a result of taking this medication, do you experience any side effects at all?
   ☐1 Yes
   ☐0 No
5. How bothersome are the side effects of the medication you take to treat your condition?
   ☐1 Extremely Bothersome
   ☐2 Very Bothersome
   ☐3 Somewhat Bothersome
   ☐4 A Little Bothersome
   ☐5 Not at All Bothersome
6. To what extent do the side effects interfere with your physical health and ability to function (i.e., strength, energy levels, etc.)?
   ☐1 A Great Deal
   ☐2 Quite a Bit
   ☐3 Somewhat
   ☐4 Minimally
   ☐5 Not at All
7. To what extent do the side effects interfere with your mental function (i.e., ability to think clearly, stay awake, etc.)?
   ☐1 A Great Deal
   ☐2 Quite a Bit
   ☐3 Somewhat
   ☐4 Minimally
   ☐5 Not at All
8. To what degree have medication side effects affected your overall satisfaction with the medication?
   ☐1 A Great Deal
   ☐2 Quite a Bit
   ☐3 Somewhat
   ☐4 Minimally
   ☐5 Not at All
9. How easy or difficult is it to use the medication in its current form?
   ☐1 Extremely Difficult
   ☐2 Very Difficult
   ☐3 Difficult
   ☐4 Somewhat Easy
   ☐5 Easy
   ☐6 Very Easy
   ☐7 Extremely Easy
10. How easy or difficult is it to plan when you will use the medication each time?
    ☐1 Extremely Difficult
    ☐2 Very Difficult
    ☐3 Difficult
    ☐4 Somewhat Easy
    ☐5 Easy
    ☐6 Very Easy
    ☐7 Extremely Easy
11. How convenient or inconvenient is it to take the medication as instructed?
    ☐1 Extremely Inconvenient
    ☐2 Very Inconvenient
    ☐3 Inconvenient
    ☐4 Somewhat Convenient
    ☐5 Convenient
    ☐6 Very Convenient
    ☐7 Extremely Convenient
12. Overall, how confident are you that taking this medication is a good thing for you?
    ☐1 Not at All Confident
    ☐2 A Little Confident
    ☐3 Somewhat Confident
    ☐4 Very Confident
    ☐5 Extremely Confident
13. How certain are you that the good things about your medication outweigh the bad things?
    ☐1 Not at All Certain
    ☐2 A Little Certain
    ☐3 Somewhat Certain
    ☐4 Very Certain
    ☐5 Extremely Certain
14. Taking all things into account, how satisfied or dissatisfied are you with this medication?
    ☐1 Extremely Dissatisfied
    ☐2 Very Dissatisfied
    ☐3 Dissatisfied
    ☐4 Somewhat Satisfied
    ☐5 Satisfied
    ☐6 Very Satisfied
    ☐7 Extremely Satisfied

SCALE SCORING ALGORITHM: TSQM Scale scores range from 0 to 100 and no computed score should be lower or higher than these limits.
EFFECTIVENESS: ([(Item 1 + Item 2 + Item 3) – 3] divided by 18) × 100
If one item is missing: ([(Sum of Item 1? + Item 2? + Item 3?)) – 2] divided by (12) × 100

TSQM Version II

CONVENIENCE: ([Sum of Item 9 to Item 11) – 3] divided by 18) × 100
If one item is missing: ([(Sum of Item9? to Item11?)) – 2] divided by (12) × 100
OVERALL SATISFACTION
First recode Item14_recode = (Item14 – 1) × 5/6
Then: ([Sum of Item 12 to Item 14) – 3] divided by (12) × 100
If any one Item is missing: ([Sum of Item 12? to Item 14?) – 2] divided by (8) × 100

APPENDIX F: RESULTS

Figure 14 : Proportion of Respondents using generic medications

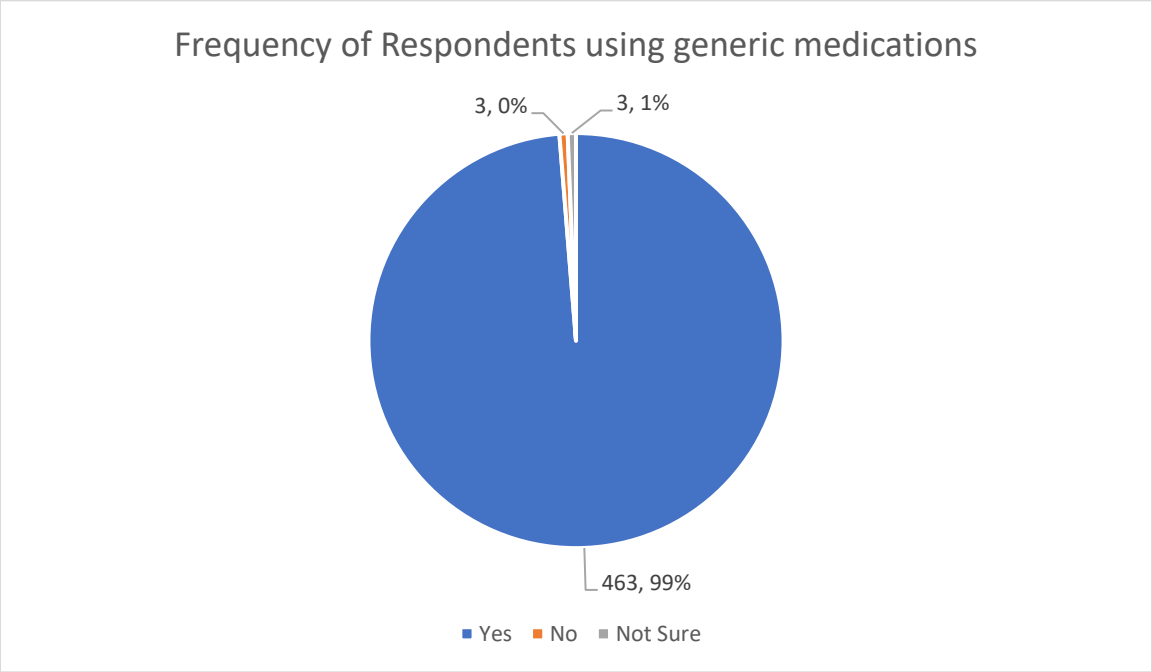


Figure 15. : Reasons for Respondents using generic medications

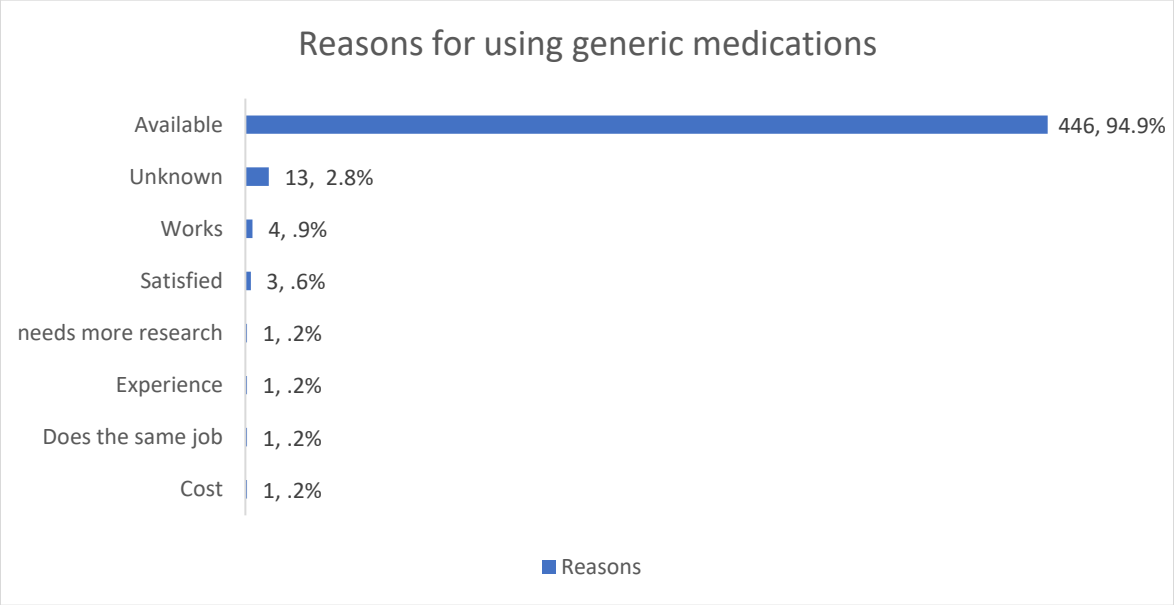


Table 8: Linear regression towards the knowledge factors on generic medications influences on satisfaction.

Coefficients[a]

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
1 (Constant)	50.173	10.120		4.958	.000	30.285	70.061
Generic medicines contain the same ingredient as the original/brand name medications.	3.044	.887	.195	3.431	.001	1.300	4.788
Generic medicines are usually interchangeable with the original/brand name medicines	.029	1.068	.002	.027	.979	-2.069	2.127
Generic medicines need to undergo clinical testing just like original/brand named medicines.	-6.532	1.861	-.174	-3.509	.000	-10.190	-2.874
Generic medicines are intended to be used the same as original/brand name medicines	-1.229	1.128	-.067	-1.090	.277	-3.447	.988
Generic medicines are important for reducing overall health cost.	1.324	1.604	.047	.826	.409	-1.827	4.475
Generic medicines provide quality care at an affordable cost.	1.320	1.301	.065	1.014	.311	-1.237	3.877
Generic medicines are cheaper as compared to original/brand name medicines.	5.386	2.647	.105	2.035	.042	.184	10.589
Generic medicines produce similar adverse reactions as original/brand name medicines.	1.032	.881	.066	1.172	.242	-.699	2.763

a. Dependent Variable: Overall_Satisfaction

Table 9: Linear regression towards the attitude factors on generic medications influences on satisfaction.

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	57.875	3.225		17.945	.000	51.537	64.213
	Generic medicines are not as safe as the original/brand name medicines.	-.670	1.131	-.053	-.593	.554	-2.892	1.551
	Generic medicines are not as effective as original/brand name medicines.	-1.487	1.151	-.119	-1.292	.197	-3.750	.775
	Generic medicines take longer to act in the body.	-.686	1.128	-.053	-.608	.543	-2.902	1.531
	Generic medicines cost less because they are inferior to the original/brand name medicines.	.506	1.017	.039	.498	.619	-1.492	2.505
	Generic medicines have doubtful efficacy in chronic diseases.	.764	.969	.060	.788	.431	-1.141	2.669
	Generic medicines take a similar time to act in the body as the original/brand name medicines.	3.534	.711	.229	4.974	.000	2.138	4.930

a. Dependent Variable: Overall_Satisfaction

MEDICATION ADHERENCE QUESTIONNAIRE

MEDICATION HEALTH LITERACY

Figure 16.1: Proportion of Respondents aware of what their medication does

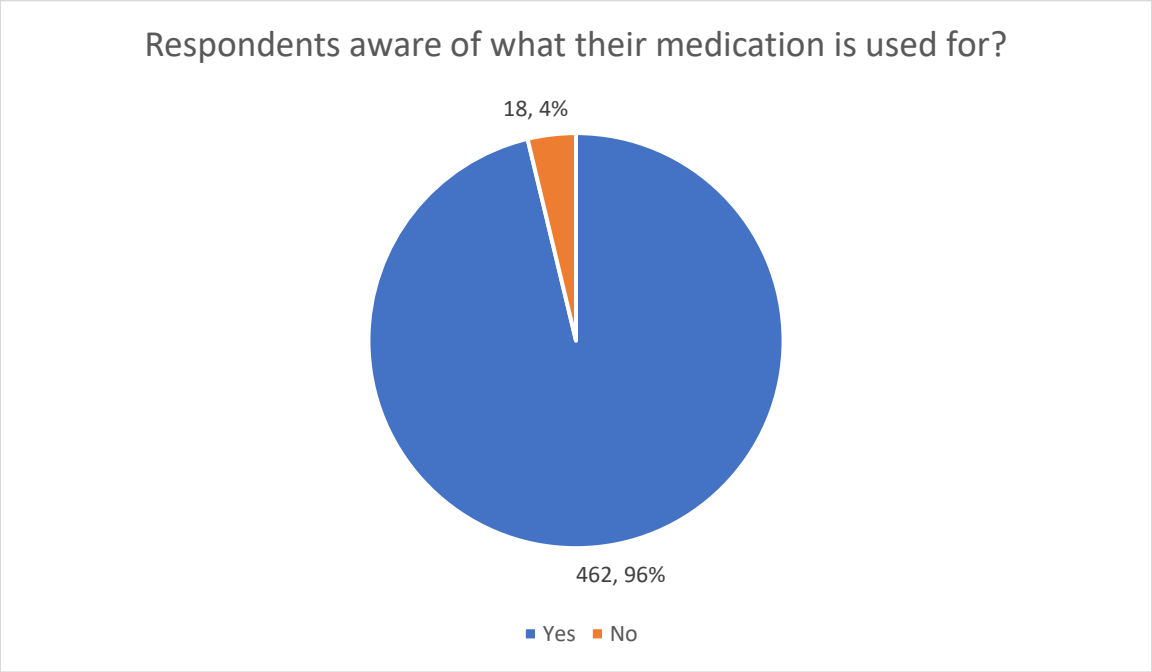
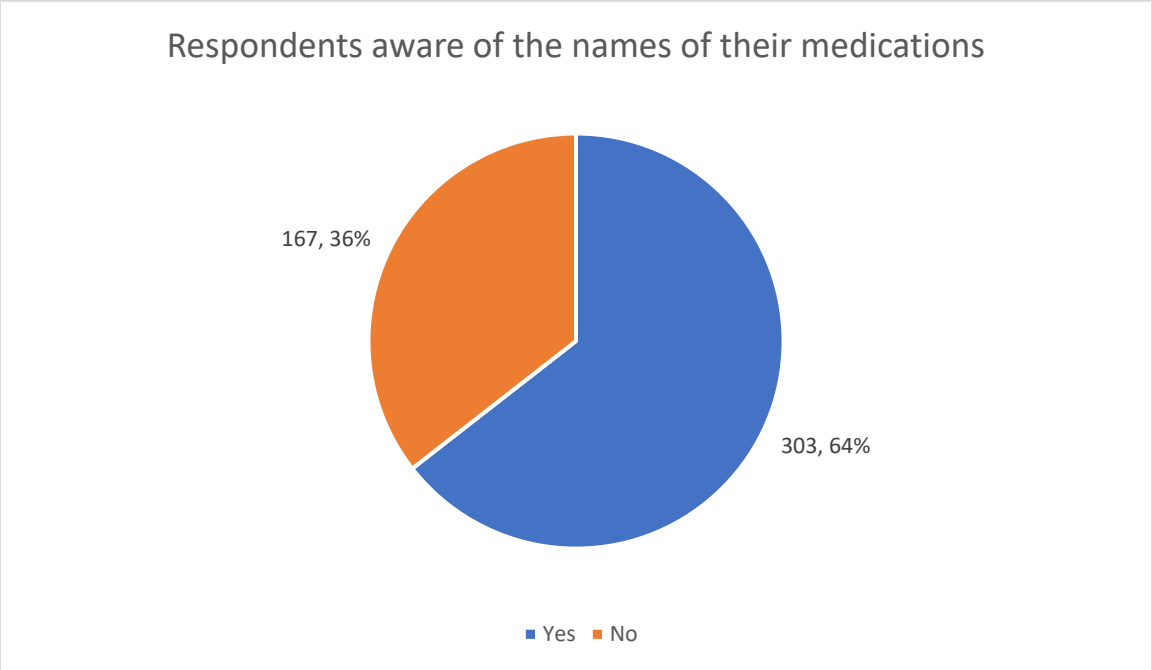


Figure 16.2: Proportion of Respondents aware of the names of their medications



POTENTIAL MEMORY PROBLEMS

Figure 17.1: Do respondents ever have trouble remembering when to take their medications?

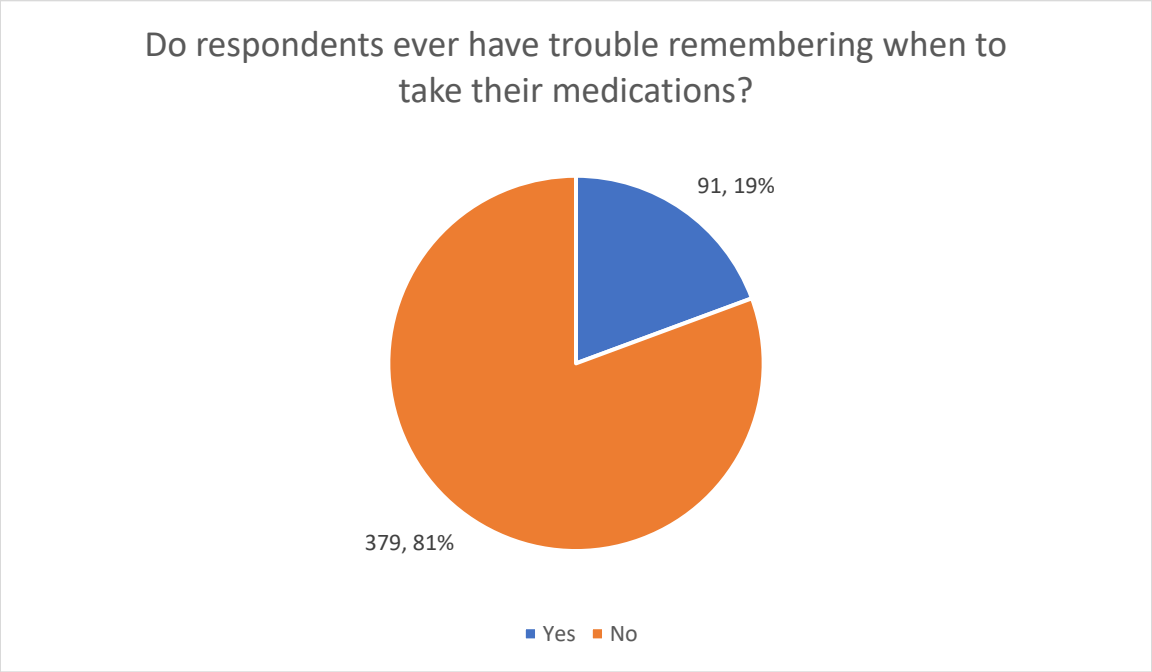


Figure 17.2: In the past 6 months, have respondents missed getting a refill or a new prescription filled on time?

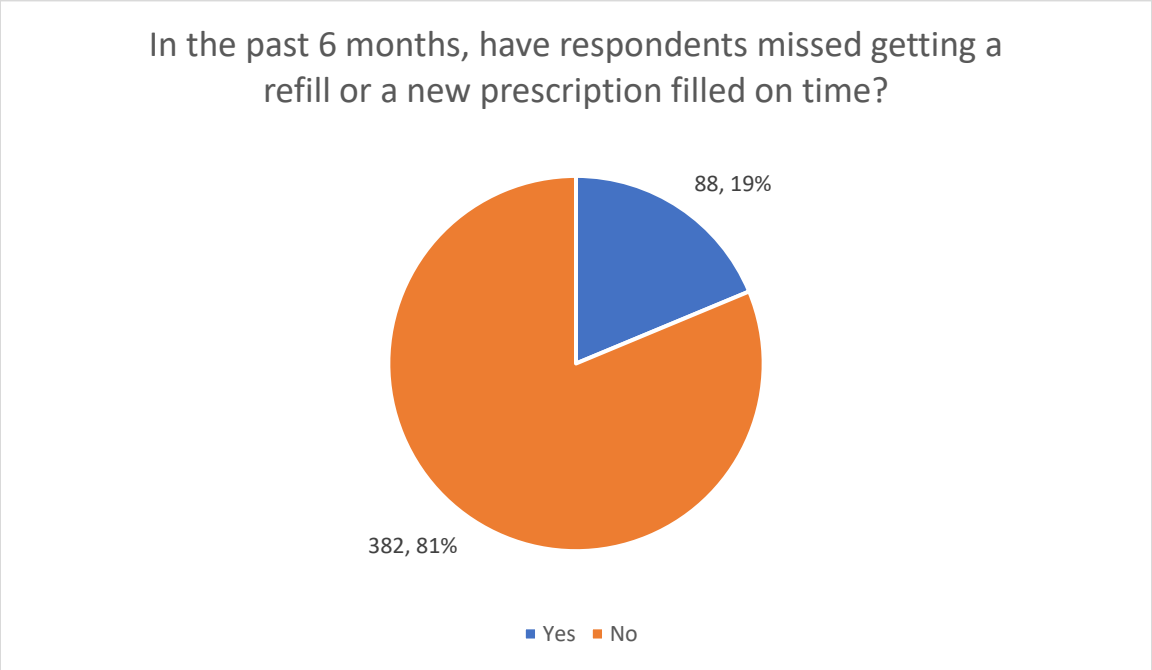


Figure 17.3: How often do respondents miss taking a dose of medication?

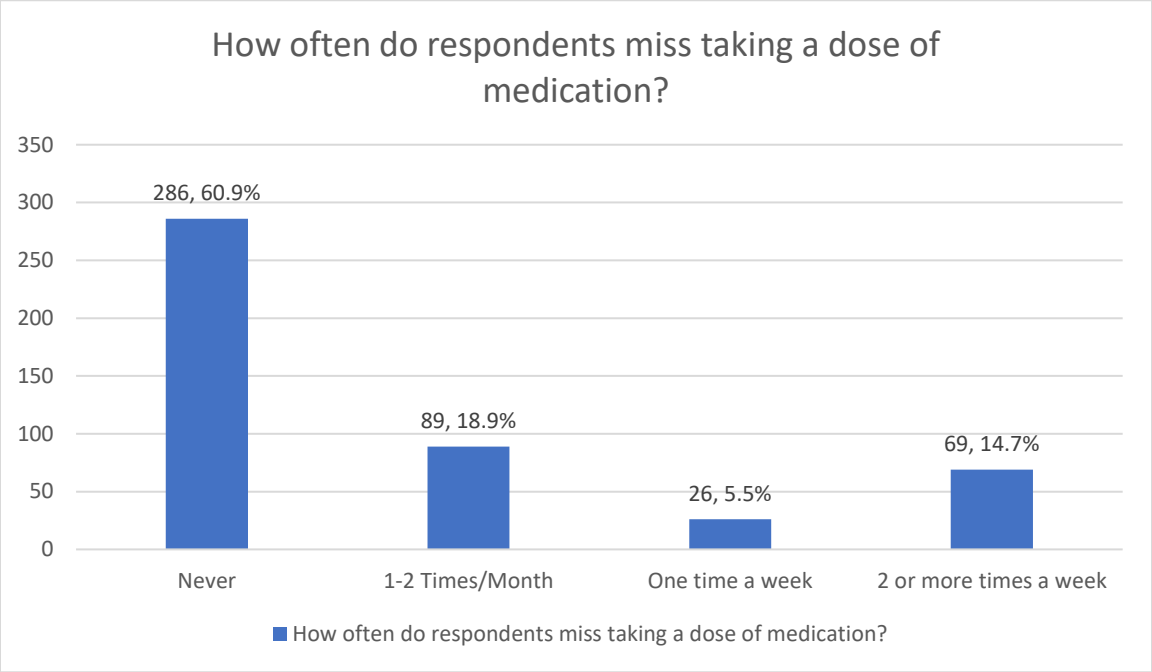
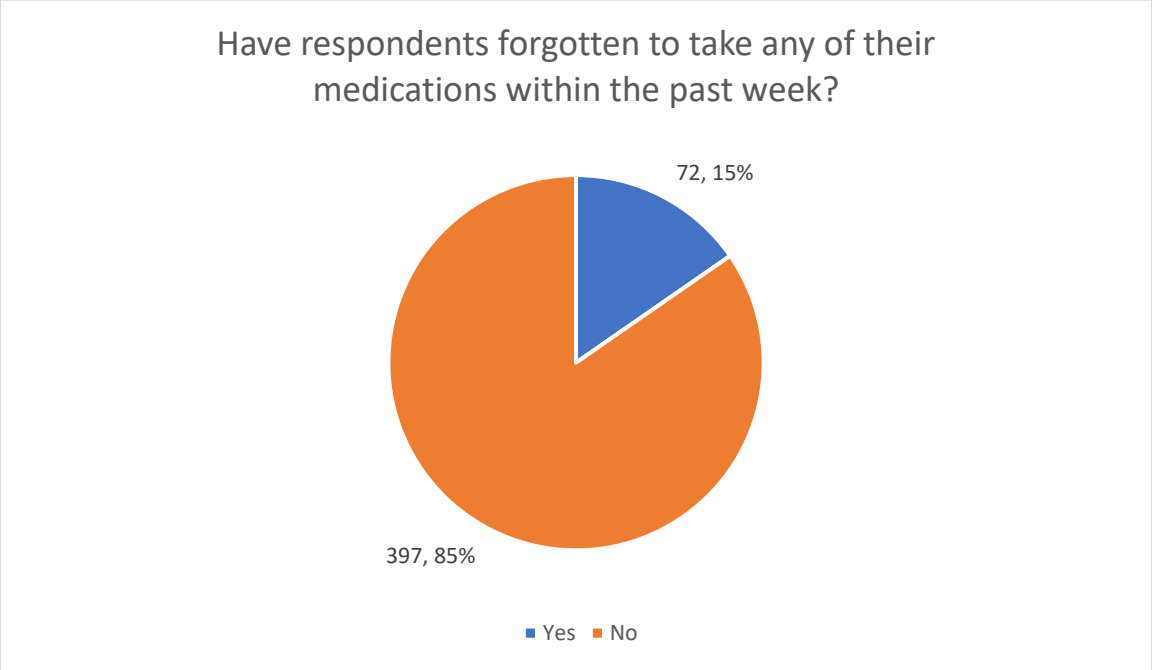


Figure 17.4: Have respondents forgotten to take any of their medications within the past week?



HEALTH BELIEFS

Figure 18.1: Do respondents ever not take medications because they feel they do not need it?

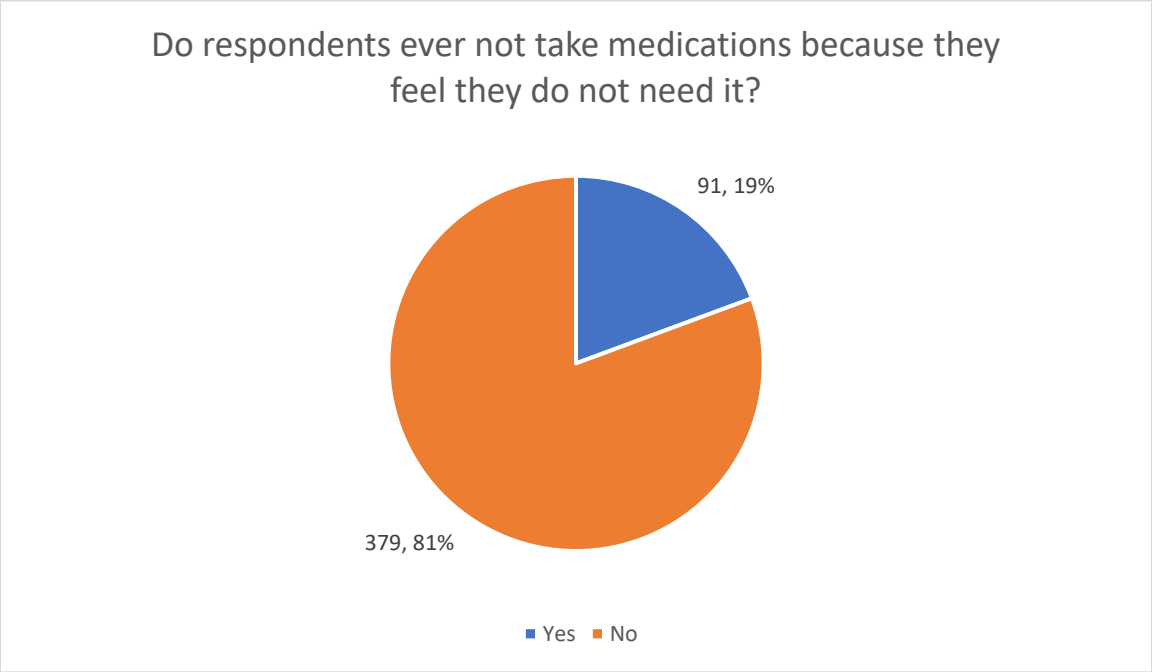


Figure 18.2: Do respondents ever think that their medications are not helping?

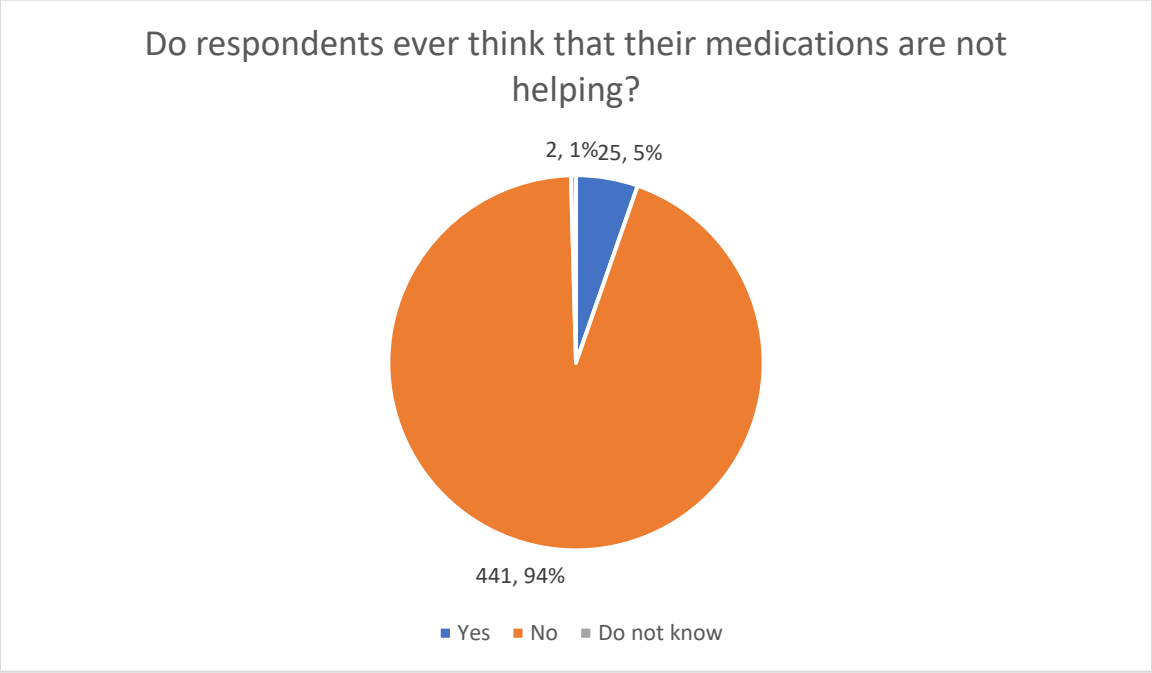
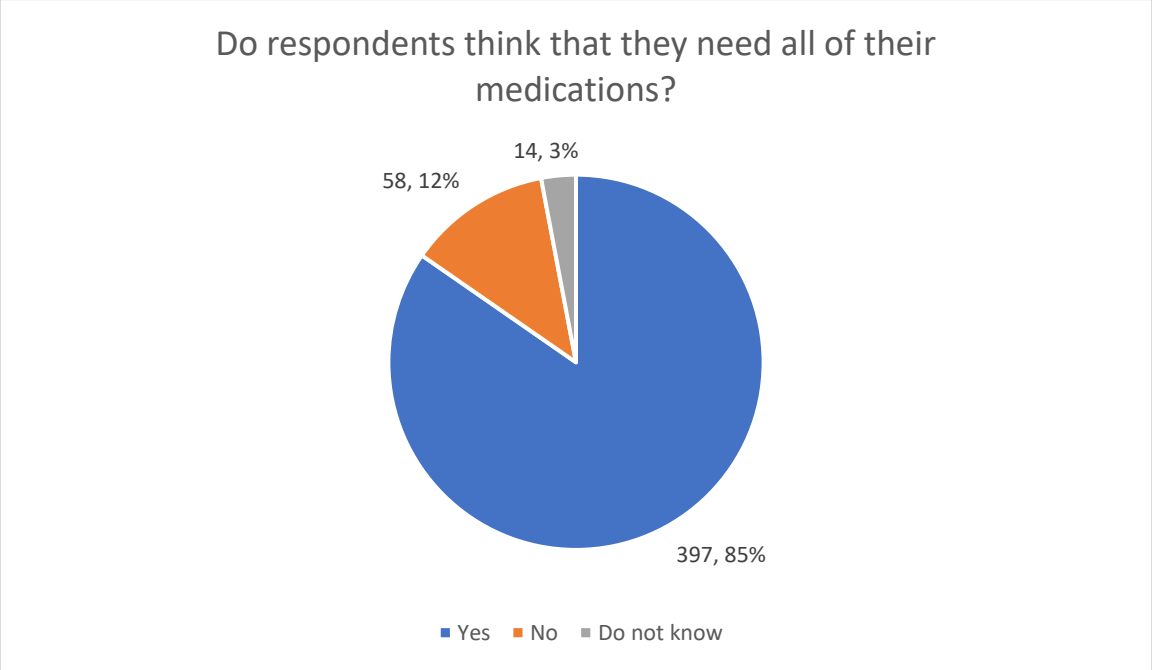


Figure 18.3: Do respondents think that they need all of their medications?



INFORMATION ON POTENTIAL PHYSICAL AND/OR FUNCTIONAL DISABILITY

Figure 19. : Do respondents have any physical problems that keep them from taking their medications as prescribed?

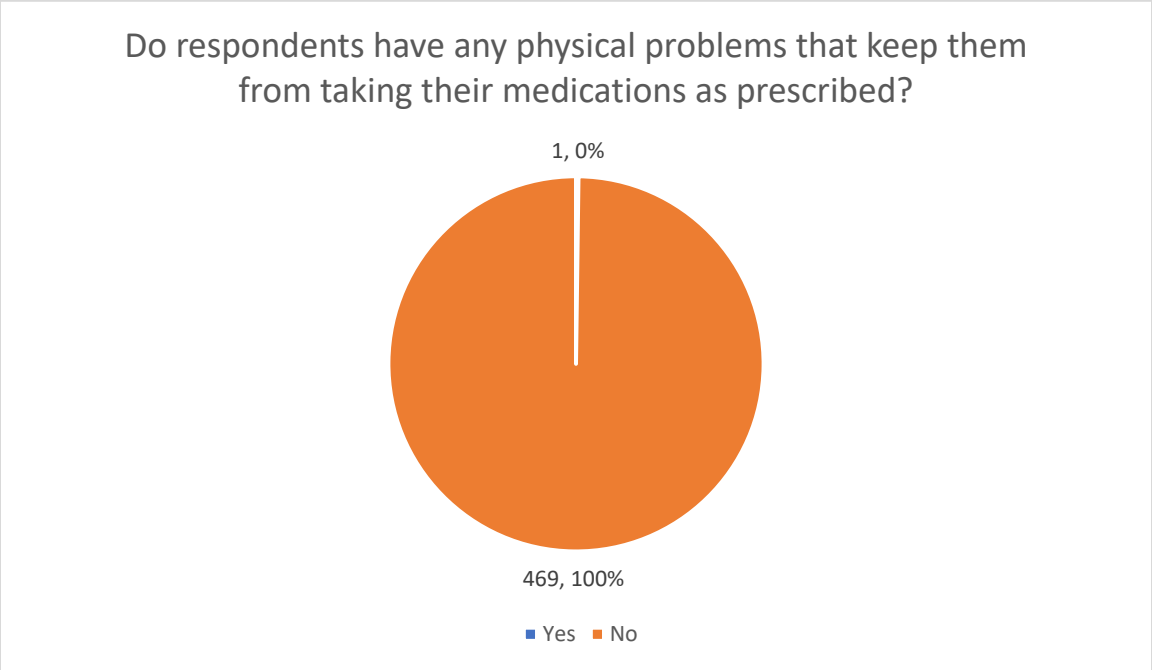
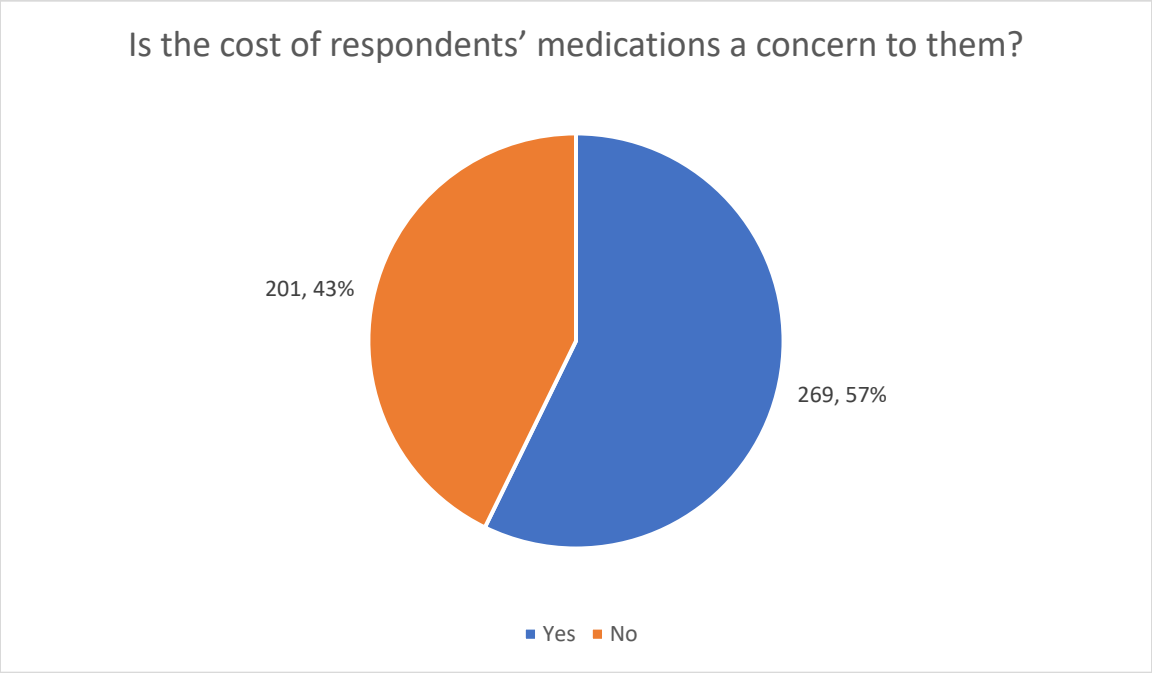


Figure 20. : Is the cost of respondents' medications a concern to them?



APPENDIX G

TIME TABLE

Research Stages	Research Tasks/Activities	Proposed Completion Dates
1	Submission of the research proposal	29th March 2019
2	Presentation of a research proposal.	29th May 2019
3	Write to the research ethics committee for approval to conduct research. Approval granted.	30th July 2019 27th September 2019
4	Write to the North Central Regional Health Authority and Medical Records Department to obtain permission to conduct a research study. Approval granted.	1st October 2019 21st October 2019
5	Pilot testing of the questionnaire. Training of research assistants	22nd October 2019 23rd October – 25th October 2019
6	Printing of questionnaires.	25th October – 26th October 2019
7	Sampling and data collection.	28th October 2019- 10th January 2020
8	Data analysis and interpretation.	11th January 2020 – 29th February 2020
9	Writing of discussion.	1st March 2020 – 29thJune 2020
10	Submission of the thesis.	30th June 2020

APPENDIX H

BUDGET FOR THE RESEARCH STUDY

1. Participant Information Sheet: 4 pages @ 35c per page

   For 470 participants: $658.00

2. Questionnaire/Survey: 10 pages @ 35c per page worked out to be $3.50 per participant

   For 470 participants: $1, 645.00

3. Travelling/Gasoline: $200.00 per month

   For the data collection period: $600.00

   TOTAL BUDGET: $2,903.00

APPENDIX I

TURNITIN REPORT

7%	2%	4%	6%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Mark J. Atkinson, Ritesh Kumar, Joseph C. Cappelleri, Steven L. Hass. "Hierarchical Construct Validity of the Treatment Satisfaction Questionnaire for Medication (TSQM Version II) among Outpatient Pharmacy Consumers", Value in Health, 2005 Publication	1%
2	Mohamed A. A. Hassali. "Consumers' views on generic medicines: A review of the literature", International Journal of Pharmacy Practice, 04/2009 Publication	<1%
3	Submitted to University of Southern California Student Paper	<1%
4	Submitted to Kingston University Student Paper	<1%

5	Submitted to Laureate Higher Education Group Student Paper	<1%
6	"Society of General Internal Medicine", Journal of General Internal Medicine, 2011 Publication	<1%
7	journals.plos.org Internet Source	<1%
8	scielosp.org Internet Source	<1%
9	Submitted to Grand Canyon University Student Paper	<1%

10	A. Villarroel Stuart, Y. Clement, P. Sealy, R. Löbenberg, L. Montane-Jaime, R. G. Maharaj, A. Maxwell. "Comparing the Dissolution Profiles of Seven Metformin Formulations in Simulated Intestinal Fluid", Dissolution Technologies, 2015 Publication	<1%
11	Straka, Robert J., Denis J. Keohane, and Larry Z. Liu. "Potential Clinical and Economic Impact of Switching Branded Medications to Generics :", American Journal of Therapeutics, 2015. Publication	<1%
12	Submitted to International Islamic University Malaysia Student Paper	<1%
13	Submitted to University of the West Indies Student Paper	<1%
14	Md. Moddassir Alam, Pallab Sikdar, Amresh Kumar, Arun Mittal. "Assessing adherence and patient satisfaction with medication", International Journal of Pharmaceutical and Healthcare Marketing, 2018 Publication	<1%

15	Submitted to Universiti Sains Malaysia Student Paper	<1%
16	Stephen P. Weinstein, Peter A. DeMaria, Michael Rosenthal. "AIDS and Alcohol: Concerns For the Physician", Hospital Practice, 2016 Publication	<1%
17	www.moe.gov.tt Internet Source	<1%
18	bmcpublichealth.biomedcentral.com Internet Source	<1%

"Pharmaceutical Policy in Countries with

19	Developing Healthcare Systems", Springer Science and Business Media LLC, 2017 Publication	<1%
20	Submitted to An-Najah National University Student Paper	<1%
21	MARTINE ROTHBLATT. "THE TERASEM MIND UPLOADING EXPERIMENT", International Journal of Machine Consciousness, 2012 Publication	<1%
22	eprints.nottingham.ac.uk Internet Source	<1%
23	Submitted to Mahidol University Student Paper	<1%
24	Submitted to University of Stirling Student Paper	<1%
25	Jean Christian Borel, Renaud Tamisier, Sonia Dias-Domingos, Marc Sapene et al. "Type of Mask May Impact on Continuous Positive Airway Pressure Adherence in Apneic Patients", PLoS ONE, 2013	<1%

Publication

26	Submitted to University of Mauritius Student Paper	<1%
27	eprints.uwe.ac.uk Internet Source	<1%
28	bmcfampract.biomedcentral.com Internet Source	<1%
29	Christine Haddad, Souheil Hallit, Mohammad Salhab, Aline Hajj et al. "Association Between Adherence to Statins, Illness Perception, Treatment Satisfaction, and Quality of Life among Lebanese patients", Journal of	<1%

Cardiovascular Pharmacology and Therapeutics, 2018

Publication

---

30 Submitted to University College London

Student Paper

<1%

---

31 Submitted to Kaplan University

Student Paper

<1%

---

32 Submitted to Universiti Kebangsaan Malaysia

Student Paper

<1%

---

33 Submitted to University of London External System

Student Paper

<1%

---

34 Kay Stewart, Alian Alrasheedy, Azmi Hassali, David Kong, Hisham Aljadhey, Mohamed Izham B Mohamed Ibrahim, Saleh Al-Tamimi. "Patient knowledge, perceptions, and acceptance of generic medicines: a comprehensive review of the current literature", Patient Intelligence, 2014

Publication

<1%

---

35 Submitted to Oxford Brookes University

Student Paper

<1%

36	Submitted to Loughborough University Student Paper	<1%
37	Peter James, Abdulai Bah, Emmanuel Margao, Christian Hanson, John Kabba, Shazia Jamshed. "Exploring the Knowledge and Perception of Generic Medicines among Final Year Undergraduate Medical, Pharmacy, and Nursing Students in Sierra Leone: A Comparative Cross-Sectional Approach", Pharmacy, 2018 Publication	<1%
[illegible]	A Warwick, A Lotery. "Genetics and genetic testing for age-related macular degeneration",	<1%

Eye, 2017

Publication

---

39 link.springer.com

Internet Source

<1%

---

40 Dam Kim, Ji-Young Choi, Soo-Kyung Cho, Chan-Bum Choi et al. "Prevalence and Associated Factors for Non-adherence in Patients with Rheumatoid Arthritis", Journal of Rheumatic Diseases, 2018

Publication

<1%

---

41 digitalcommons.wayne.edu

Internet Source

<1%

---

42 Andréa D. Bertoldi, Aluísio J. D. Barros, Pedro C. Hallal. "Generic drugs in Brazil: known by many, used by few", Cadernos de Saúde Pública, 2005

Publication

<1%

---

43 Submitted to University of Brighton

Student Paper

<1%

---

44 onlinelibrary.wiley.com

Internet Source

<1%

45	epdf.pub Internet Source	<1%
46	Submitted to The University of Manchester Student Paper	<1%
47	Submitted to University of Southampton Student Paper	<1%
48	Mark J. Atkinson. "Hierarchical Construct Validity of the Treatment Satisfaction Questionnaire for Medication (TSQM Version II) among Outpatient Pharmacy Consumers", Value in Health, 11/2005 Publication	<1%

49	Miguel A. Ruiz, José Ramón González-Porras, José Luis Aranguren, Eduardo Franco et al. "Development and validation of a new questionnaire measuring treatment satisfaction in patients with non-valvular atrial fibrillation: SAFUCA®", Quality of Life Research, 2016 Publication	<1%
50	Submitted to University of Essex Student Paper	<1%
51	JOANNE CHAPMAN. "Testing the sensitivity, specificity and feasibility of four falls risk assessment tools in a clinical setting : Falls risk assessment", Journal of Nursing Management, 01/2011 Publication	<1%
52	Submitted to University of Huddersfield Student Paper	<1%
53	commons.bcit.ca Internet Source	<1%
54	www.tandfonline.com Internet Source	<1%

55	www.researchsquare.com Internet Source	<1%
56	open.uct.ac.za Internet Source	<1%
57	Submitted to Anglia Ruskin University Student Paper	<1%
58	Submitted to Ventura County Community College District Student Paper	<1%
59	Submitted to Indian Institute of Public Health Gandhinagar Student Paper	<1%

60	Antonín Pavlíček. "chapter 9 Social Media and Creativity", IGI Global, 2017 Publication	<1%
61	Submitted to Clayton College & State University Student Paper	<1%
62	www.ajournal.co.uk Internet Source	<1%
63	Submitted to University of Duhok Student Paper	<1%
64	mpra.ub.uni-muenchen.de Internet Source	<1%
65	Submitted to The Robert Gordon University Student Paper	<1%
66	clok.uclan.ac.uk Internet Source	<1%
67	Submitted to University of Ulster Student Paper	<1%
68	Submitted to University of East London Student Paper	<1%

69	J. Gadea, C. Matás. "Sperm factors related to in vitro penetration of porcine oocytes", Theriogenology, 2000 Publication	<1%
70	eprints.chi.ac.uk Internet Source	<1%
71	Submitted to Southville International School and Colleges Student Paper	<1%
72	Submitted to EDMC Student Paper	<1%
73	Submitted to Intercollege Student Paper	<1%

74	Submitted to Eiffel Corporation Student Paper	<1%
75	Mark J Atkinson. Health and Quality of Life Outcomes, 2004 Publication	<1%
76	Submitted to Management & Science University Student Paper	<1%
77	Submitted to University of Bristol Student Paper	<1%
78	Sameer Dhingra, Sandeep Maharaj, Rian Marie Extavour, Zaheer-Ud-Din Babar. "Chapter 17 Pharmaceutical Policy in Trinidad and Tobago", Springer Science and Business Media LLC, 2017 Publication	<1%