

**PATIENT RELATED FACTORS ASSOCIATED WITH GLYCAEMIC
CONTROL IN TYPE II DIABETIC PATIENTS WITHIN THE
NORTHCENTRAL REGIONAL HEALTH AUTHORITY
TRINIDAD**

A Thesis

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ABSTRACT

Patient Related Factors associated with Glycaemic Control in Type II Diabetic Patients within the Northcentral Regional Health Authority Trinidad

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Background and Objectives: Preventative healthcare practices continues to be the basis for prevention of diabetes related complications. Established guidelines are likely to decrease the incidence of diabetes complications, however, patient related factors either perceived or real, prevent the utilization of medical services resulting in poorer health outcomes. The aim of this study was to identify the patient related factors leading to elevated HbA1c levels in type 2 diabetic patients at the health centres within the Northcentral Regional Health Authority, Trinidad and to determine the association between patient related factors and optimal glycaemic control as measured by HbA1c levels.

Subjects and Methods: This was a cross-sectional study using convenience sampling of participants who were type II diabetics, over the age of 18 years, attending the chronic disease clinic for their usual appointment within selected health centres of the Northcentral Regional Health Authority during the period January 2018 to March 2018. After receiving ethical approvals and informed consent, a de novo, pretested self-administered and researcher-assisted survey was administered. Patients' barriers were determined by using the Independent Samples T test and Analysis of Variance in 2 groups of patients.

Results: 254 subjects participated in this study with a response was 87.6% There were 7 patient related factors associated with glycaemic control identified based on the analysis of 200 patients with recorded HbA1c in this survey. The mean HbA1c was 8.360 with SD 2.062. Age (55-64years age group), use of insulin, emotional problems and anxiety were associated with higher mean HbA1c. Use of oral hypoglycaemic agents, personal responsibility for diabetes care and being retired were also associated with lower mean HbA1c.

Conclusion: This study identified several patient related predictors of glycaemic control based on the mean HbA1c in the public health system in parts of North and Central Trinidad. Implementation of relevant interventional programs are needed to remove these factors and improve patient outcomes.

Keywords: diabetes mellitus; barriers; self-care behaviours; compliance, and adherence.

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Table of Contents

ABSTRACT.....	ii
Acknowledgement.....	iii
List of Figures and Tables.....	vi
Introduction.....	1
Background/Rationale	1
Aims/Objectives.....	15
Methodology	16
Study Design	16
Location.....	16
Sample size calculation	16
Population	16
Inclusion criteria	17
Exclusion criteria.....	17
Instrument development.....	17
Conceptual Model	18
Validating Strategy and Pretesting Instrument	18
Ethical Considerations.....	20
Data Collection	20
Analysis Strategy.....	21
Results	22
Socio-Demographics.....	22
Discussion.....	50
Impact of this study.....	55

Strengths of study	55
Limitations	55
Bias and challenges	56
Recommendations	57
Conclusion	59
Research Budget	60
Research Timeline	61
References	62
Appendix 1	70
Appendix 2	74
Appendix 3	75

List of Figures and Tables

Figure 1: Conceptual model.....	18
Figure 2: Data collection.....	20
Table 1: Ethnicity.....	22
Table 2: Highest level of education.....	23
Table 3: Current employment status.....	23
Table 4: Communication.....	24
Table 5: Family support.....	26
Table 6: Use of medication.....	27
Table 7: Glucose monitoring.....	29
Table 8: Meal plan.....	29
Table 9: Exercise.....	31
Table 10: Cultural factors.....	32
Table 11: Motivation.....	35
Table 12: Health risk.....	37
Table 13: Mental and physical health.....	39
Table 14: Factors associated with Higher mean HbA1c.....	42
Table 15: Factors associated with Lower mean HbA1c.....	43
Table 16: Results for PHQ-9 for Depression	43
Table 17: Factors associated with Higher Mean HbA1c: Age.....	44

Table 18: Factors associated with Higher Mean HbA1c: Use of insulin.....	45
Table 19: Factors associated with Higher Mean HbA1c: Emotional problems....	45
Table 20: Factors associated with Higher Mean HbA1c: Anxiety.....	46
Table 21: Factors associated with Lower Mean HbA1c: Employment Status.....	47
Table 22: Factors associated with Lower Mean HbA1c: Use of oral hypoglycaemic agents.....	48
Table 23: Factors associated with Lower Mean HbA1c: Personal responsibility for diabetes care.....	48
Table 24: Comparison of Findings.....	50
Table 25: Barriers to diabetes care reported by previous studies and considered in this study.....	51
Table 26: Budget.....	60
Table 27: Research Timeline.....	61

Introduction

Background/Rationale

There are many factors that influence health. Many of these factors have complex interactions between genetic factors, health behaviour, environmental factors, socioeconomic factors and health services which affect the wellbeing of individuals. These determinants of health, influence the health of the wider population and by extension life expectancy.

According to the Health Card for Trinidad and Tobago, 2011, ¹ life expectancy, can be defined as the expected life span of a new-born given the existing health conditions. It is therefore an indicator of the general health for a given population. In 2006 the life expectancy for the entire population of Trinidad and Tobago was 71 year, for males 66 years and for females 72 years.

For the same period, the average life span for males was 72 years and for females, 79 years in Barbados. Likewise in Jamaica males and females had an average life span of 69 and 75 years respectively. Hence, even though the life expectancy of Trinidad and Tobago is improving, it is doing so at a slower rate compared to our Caribbean neighbours.

The health status of a given population is also reflected in the number and rates of underlying causes of death. In Trinidad and Tobago the top five causes of death, males and females combined, are Cardiovascular Disease (24.6%), Malignant Neoplasm (13.7%), Diabetes Mellitus (13.6%), Cerebrovascular Disease (9%) and External Causes of injuries (10.6%).^{1, 2}

This means that chronic noncommunicable diseases (CNCDs) accounts for about 60% of the major causes of death. This was highlighted in 2007, where the CARICOM heads of Government expressed their commitment to decrease the burden of CNCDs in the Caribbean through an extensive and integrated prevention and control strategies.

In Trinidad and Tobago this responsibility was placed on the five Regional Health Authorities (RHAs). Each RHA has a comprehensive network of at least one hospital, several polyclinics/District Health Facilities (DHF) and health centres

providing a range of services and a referral system between levels. All services and medications are free to clients and was expanded to all citizens with the addition of the Chronic Disease Assistance Programme (CDAP) in the treatment of chronic conditions: asthma, high blood pressure, diabetes, cardiac disease, mental depression, benign prostatic hyperplasia, glaucoma, Parkinson's disease, arthritis and epilepsy. The strategy for improving health care delivery included collaborating with the private health sector and having arrangements with international professionals and organisations.¹

According to a report by the Pan American Health organisation, 2012 the cost of health care continues to rise in Trinidad and Tobago, US\$608,990,080 in 2010, and is mainly attributable to CNCDS.²

This study seeks to uncover the personal barriers, defined as “a circumstance or obstacle that keeps people or things apart or prevents communication or progress”³, that patients struggle with in self-management of diabetes. Most of the local studies done looked at barriers as perceived by health professionals and at system or institutional levels. Studies on patient's personal barriers are very few and have not considered identifying barriers and quantifying the impact on current guidelines on diabetes management. Previous local studies did not identify or quantify the personal barriers impacting on patients' ability to carry out instructions in diabetes care and prevention of long-term complications. Investigation of these deeper issues with reviewing and restructuring the current health model with respect to routine revisits are likely to improve patient health outcomes. Often at health centres within the Regional Health Authorities in Trinidad, where health promotion is carried out daily, some patients continue to have elevated HbA1c levels resulting in renal failure, myocardial infarction, cerebrovascular accidents, diabetic retinopathy and major amputations.

The cornerstone of primary and secondary prevention of diabetes related complications continues to be preventative healthcare practices. Established guidelines from the American Diabetes Association and the Diabetes Quality Improvement Project are evidence based and form part of the primary health care

practices in many countries around the world afflicted with diabetes, and if followed, are likely to decrease the incidence of diabetes complications by improving the standards of medical care. However, patient barriers either perceived or real, prevent the utilization of medical services leading to many patients not seeking timely medical care, resulting in poorer health outcomes.⁴

Estimations from the World Health Organization (WHO) suggest that over 346 million individuals are diagnosed with diabetes mellitus worldwide. By the year 2030 this number will likely double if appropriate interventions are not applied.⁵

Trinidad and Tobago occupies about 5,128 km, of which Trinidad occupies 4828 km, ⁶ situated in the most southwestern part of the Caribbean next to Venezuela and is considered the gateway to the Americas. When compared to other Caribbean countries, Trinidad and Tobago is seen as one of the wealthiest nations in the region, being one of the largest oil and natural gas producer. The energy sector accounts for about 45% of the Gross Domestic Product (GDP) and 80% of its export. Trinidad and Tobago is considered the financial centre of the Caribbean since it has one of the highest income per capita in Latin America.

According to the Ministry of Foreign and CARICOM Affairs, one of the top priorities of Trinidad and Tobago was the implementation of the CARICOM Single Market and Economy (CSME). The CSME created a single enlarged economic space with the removal of certain restrictions which allowed the free movement of technology, persons, goods, capital and services. It also gave the right to CARICOM nationals the ability to set up businesses in any participating CARICOM Member State.⁷ This arrangement has resulted in thousands of foreigners of different races and ethnicity, migrating to work in Trinidad.

According to the Trinidad and Tobago Demographics Profile 2016: the ethnic composition of African is 34.2%, East Indian 35.4%, mixed African/East Indian 7.7%, unspecified 6.2%, mixed - other 15.3%, and other 1.3%. ⁸ All persons are allowed access to medical services in the public health sector including primary and secondary health care services which come with the associated management of medical problems including diabetes.

The chronic disease situation in the Caribbean is no different from the global one. According to a report by the Caribbean Commission on Health and Development (CCHD), non-communicable diseases (NCDs), HIV/AIDS and the health sequelae of injuries and violence, were major health concerns in the Caribbean between 1985 and 2000. During the period 1995 and 2000, diabetes mellitus and hypertension related diseases were the fastest growing causes of death, in the Caribbean Epidemiology Centre (CAREC) member countries, apart from HIV/AIDS.⁹

In the Bahamas, Barbados and Jamaica, hypertension placed a greater economic burden than diabetes, where as in Trinidad and Tobago the cost of diabetes and its associated complications were greater. On a per capita basis, among the four countries, diabetes represented the higher economic burden and ranged from 8% of GDP in Trinidad and Tobago to 1.36% in the Bahamas.

A World Health Organization (WHO) report stated that just about 15% of the general adult population has diabetes mellitus in Trinidad and Tobago.¹⁰ The cost of treating diabetes and its associated complications has been projected to increase in the coming years and all affected countries must be aware that this would constitute a large percentage of GDP, according to Arredondo and Zuniga 2006,¹¹ thus constituting enormous health and economic burdens to affected individuals and to the national economy as a whole.¹² In 2001 the estimated economic burden of diabetes amounted to TT\$2.91 billion or US\$467 million for Trinidad and Tobago.¹³

In 2015,¹⁴ a local study by Roopnarinesingh and others, concluded that there was a need to further investigate patient and system-barriers in order to improve diabetes care both within the Caribbean as well as externally, by improving and facilitating interventions to improve standards of care for diabetic patients.

Patients are likely to benefit from increased confidence levels in self-management of their diabetes leading to reduced numbers of referrals to specialist clinics for major lower limb amputations, ophthalmological procedures, treatment of cardiac disease, haemodialysis and disabilities from cerebrovascular accidents leading to

increased years of productive work and higher household incomes. Overall improved health outcomes will decrease the need for government spending on surgical procedures, rehabilitation and disability grants resulting in significant fiscal savings.

Many facets of a patient's life can prove as obstacles to good diabetes self-care and striving towards health care outcome targets can be especially difficult in the patient-centred model used in primary care practice. It is therefore important that health care professionals be able to recognise and identify barriers to self-care management.

Despite the widespread use and availability of evidence-based guidelines,¹⁵ and improvements in delivery of care, many patients with diabetes still have not achieved the recommended blood pressure, cholesterol and glycaemic levels.¹⁶ In most countries, the management of diabetes is undertaken in primary care centres using elements of the chronic disease care model,¹⁷ in particular, dedicated review clinics and shared care with specialist.¹⁸ In 2012, a systematic review and meta-analysis reviewed 94 patient randomised controlled trials, including 38,664 patients and 48 cluster randomised controlled trials, including 2538 clusters and 84,865 patients to assess the effects of quality improvement (QI) strategies on glycated haemoglobin (HbA1c), microvascular complication monitoring, smoking cessation and vascular risk management in patients with diabetes. It was found that many trials of quality improvements showed significant improvements in diabetes care and has called for the use of quality improvements as a vital component of any interventions used to improve diabetes management.¹⁹ It is reasonable to suggest therefore, that the quality improvements used, be based on an understanding of the barrier to diabetes care that exist in patients.

In February 2016 a qualitative systematic review was done to guide quality improvement strategies for type 2 diabetes based on the synthesis of evidence of primary care nurses' and physicians' perceived influences on care. The systematic review stated that clinicians have recognised that patient's socioeconomic and occupational circumstances play a significant problem in enabling self-

management.¹⁶ This review was published in the British Journal of General practice where a total of 32 studies were included: 11 addressed glycaemic control, 3 blood pressure, 1 cholesterol control and 17 general diabetes care. This was translated into a continued policy agenda for promoting self-management, but physicians often found it difficult to have shared responsibility effectively with patients and support behaviour change.¹⁶ There has been improvement in the structure of clinical management of type 2 diabetes. A meta-analysis of randomised control trials by Tricco and colleagues,¹⁹ suggest that improvements in systematic chronic disease management and patient involvement was particularly effective in achieving treatment goals.²⁰

A good indicator of metabolic control is the use of home blood glucose monitors and measurement of glycosylated haemoglobin as this shifted more responsibility to patients with diabetes and has contributed to self-care.²¹ A study in April 2003, defined self-care in diabetes as “an evolutionary process of development of knowledge or awareness with the complex nature of the diabetes in a social context”.²² In 2008 the American Association of Diabetes Educators outline seven essential self-care behaviour in diabetic patients which predicts good outcomes. These are monitoring of blood glucose, healthy eating, compliance with medication, physical activity, risk-reduction behaviours, adequate problem solving skills, and healthy coping skills.²³ These behaviours have been found to be positively associated with good glycaemic control, decreased complications of diabetes, improved quality of life and represents the self-care activities required for successful diabetes management.²⁴ This is particularly so in patients with a higher level of self-confidence.²⁵ Although seen as undependable, the most cost-effective approach to self-care assessment is self-reporting and patients participating in their own care has been shown to make dramatic improvements in their disease progression.²³

Patients are expected to follow positive lifestyle behaviours which includes taking medications as indicated (this includes insulin and oral hypoglycaemic agents), following an appropriate meal plan, regular physical activities (recommended by

the American College of Sport Medicine),²⁶ monitoring of blood glucose levels, following foot care guidelines, understanding diabetes-related symptoms and seeking timely medical treatment for health-related problems.²⁷ The proposed regimen must be integrated in the patient's daily routine and becomes further complicated by patient factors including knowledge about diabetes, adherence to treatment schedules, cultural beliefs and behaviours, language barriers, financial resources, health literacy, social and family support.²⁸ Shrivastava et al, stated that clinicians should be able to recognise patient factors leading to non-compliance and effectively manage them and recommended that research particularly in developing countries, is needed to ascertain patients' perception of their diabetes self-care management in order to use resources more efficiently in diabetes management.²⁹

In 2007, a study by Simmons and others,³⁰ sought to compare diabetes care to perceived barriers between different health professional groups and individuals with diabetes. Other studies like the Diabetes Attitudes Wishes and Needs (DAWN) Study, showed that there is a high proportion of diabetic patients with diabetes related depression and an overall poor state of psychological wellbeing the DAWN study demonstrated psychological barriers to be a significant barrier in patients affected by diabetes.³¹

Knowledge about the perceptions of barriers can guide health service providers to set priorities for diabetes care at the level of service delivery. These perceptions are likely to differ between primary and secondary care providers and patients.

The hypothesis tested in this study, was that perceptions of barriers to diabetes care is significantly different between both primary and secondary health care professional groups and patients.

This was a cross-sectional study using a postal survey of hospital medical, nursing, and dietetic staff and patients, general practitioners, practice nurses across the Waikato district, New Zealand.

The persons targeted in this study came from the eye screening registry or from those who were seen in the diabetes or ophthalmology service clinics within the last 2 years

The survey instrument consisted of the four-item “Barriers to Diabetes Care” open-question which was tailored to patient or health professional situations and 7 questions for health workers or 14 questions for patients (including age, ethnicity and sex).

Among patients and general practitioners the most frequently reported perceived barriers were psychological. The results showed that psychological barriers were the most frequently reported barrier for both patients and general practitioners. This study has shown within a relatively large geographic area employing the strictness of the diabetes regimen, including exercise, dietary, clinician review, self-glucose monitoring and medication self-care behaviours, that psychological issues continues to be one of the most important perceived barriers in the management of patients with diabetes.

The results suggest that the psychological need among patients with diabetes is still not recognised as a high priority. Even though interventions for psychological and psychosocial problems have advanced, it has been shown that the evidence for the efficacy of the “pure” psychological interventions remains limited.^{32, 33}

The study suggest that there is a large gap in the development and introduction of psychological and behavioural interventions and this remains a significant barrier in the management of diabetes. As such psychological support for patients should receive a higher priority at the primary care level.

In Trinidad, it has been well documented that the prevalence of depression in diabetic patients is unacceptably high. This suggest that psychological issues may constitute a significant personal barrier to diabetes care and there is an urgent need to develop and apply appropriate interventions at a primary care level.

A review in 2009,³⁴ argued that an individual’s ability to understand and act on a health care provider’s instruction is influenced by the cultural beliefs surrounding

health and illness. Failure to consider these beliefs are unlikely to fully address the needs of those suffering from low health literacy, defined as the inability to understand or act on medical or therapeutic instructions. Trinidad is a multi-ethnic, multicultural society where cultural beliefs and practices play an important role in the daily life of many citizens. These practices and beliefs may constitute a significant personal barrier, yet to be quantified to patients with diabetes, further studies are needed.

J.M. Daly et al,³⁵ looked at patients with type 2 diabetes mellitus and assessed their attitudes, behaviours and outcomes. This was an observational study that examined a sample of 253 patients with type 2 diabetes in the United States. It looked at a conceptual model for factors influencing HbA1c and designed a self-care behaviour survey tool with the factors influencing diabetes adherence to include personal factors for example, duration of diabetes and psycho-social factors; patient-provider interactions; potential barriers to diabetes management and family support. The study tested the association of several barriers to self-care behaviours with HbA1c levels. It was found that following a meal plan and monitoring blood glucose levels were significant barriers to self-care behaviours; there was better glycaemic control associated with improved physician-client communication; the younger age group, lack of family support and poor mental health were associated with higher HbA1c levels. This was however comparable to previous studies.^{36, 37} This study created an adherence-satisfaction score for each self-care behaviour which was higher for taking medication and blood glucose testing, which were strongly associated with lower HbA1c levels. This study however did not look at a diverse population and the fact that the sample came from an academic health centre means that these findings may not apply to other clinical settings around the world. Hence there is a need to study developing countries with a diverse population.

In a 1998 study by Simmons,³⁸ and others, perceived barriers to diabetes care was both identified and quantified in a multi-ethnic urban community. This reflected the ethnic differences in the level of control of diabetes and its complications

based on the perception and experiences of patients.^{16, 18} A combined epidemiological and qualitative approach was used to define the potential barriers in patients from the perspectives of both health workers and patients. This anthropological survey identified thirty patient-identified barriers to care which were categorised into five different domains including knowledge psychological, internal physical, community and psycho-social barriers. Although barriers were similar for ethnic groups their impact and the actions needed to overcome them often differ for different regional, national, socio-economic and ethnic groups. Treatment strategies need to be tailored to overcome the barriers to care for diabetes in multi-ethnic populations. This study concluded that the results formed a framework which could allow communities to systematically identify and address barriers to diabetes care within their health care systems.³⁸

Many people living with diabetes are not meeting the recommended best practice guidelines,³⁹ however between 46-56 percent of diabetic patients meet acceptable target HbA1c of less than 7 %. A local study in 2015 looked at patient perception to insulin therapy. The study looked at a sample of just over 400 individual in 4 Regional Health Authorities (RHAs) that make up the public health system in Trinidad. It was found that for patients who did not use insulin, education, ethnicity and RHA were not predictive of glycaemic control. For those who used insulin, age, ethnicity, education level, gender and RHA were not predictive for any of the barriers to diabetes care. For persons not on insulin, only education was predictive of a barrier to insulin use.⁴⁰ A systematic review looking at self-management education program noted that such program are effective on the short term, but needs to be culturally based.⁴¹

In 2006, the West Indian Medical Journal,⁴² published a study by Wint and others, which set out to explore the Jamaican's knowledge of motivational factors, diabetes and to further identify potential barriers to glycaemic control and positive lifestyle changes. A random sample was generated from a computer where 98 women and 35 men with diabetes from a specialist outpatient clinic was selected. Each participant was subjected to a one hour in-depth interview using an

interview schedule which was pretested. The data collection instrument included domains for lifestyle changes, demographics, dietary recall, physical activity, medication use, family support, barriers to change, motivation to implement changes, and make suggestions to facilitate change.

The results showed that 71% of Jamaicans reported the need for more education. 12% thought that doctors needed to spend more time educating patients about diabetes and its complications, 7.5% thought that doctors should be more assertive with clients, and 12.7% reported the need for financial assistance.

This study concluded that there was a positive correlation between higher levels of education and a better understanding of diabetes, as opposed to those with a lower education level who will require special attention. This study also recognised that education was frequently neglected in diabetes management. Trained diabetes educators were made an indispensable part of medical services due to the findings of this study. In Trinidad, the need for diabetic educators was recognised within the last ten years and is now part of a routine diabetic clinic.

In a 2002 study,⁴³ the role of systemic factors, physicians and patients in type 2 diabetic management was examined, patient barriers were identified from the perspective of physicians, such as, patients' lack of acceptance which was evidenced by the inability to make the necessary lifestyle changes. Failing to recognise the seriousness of their condition was identified based on the fact that patients waited until it was too late and complications of diabetes occurred. Another barrier was the lack of patient adherence, this was viewed by physicians as more of a lack of motivation, since patients preferred to have something done to them rather than taking their medication. Some patients were fatalistic in their thinking and others had unrealistic perspectives, for example, using a fortune-teller to decide on how long they would live. Other barriers identified were: other co-morbidities such as renal failure; viewing life in a cultural context; cost of medication; shift work, in that patients said they were afraid of losing their job if they attended clinics and lastly education since patients continue to abuse alcohol and have poor eating habits. This study concluded that in order to accomplish

behaviour change, this had to be done in the context of promoting self-care behaviours based on a relationship between patient and health care provider.⁴³ This, therefore, depends on understanding the specific personal barriers that patients are faced with on a daily basis.

In a 2012, the West Indian Medical Journal supplement, the CHRC, reported on a study on diabetes therapeutic targets in Trinidad which evaluated the overall quality of diabetes care in Trinidad using Diabetes Quality Improvement Project (DQIP). This was a cross-sectional survey in 10 primary care facilities on type 2 diabetic patients. The study found that most of the patients from a sampled of 662 did not have frequent evaluation for prevention and management of vascular complication, approximately 50 percent had HbA1c measurements taken, whereas 65 percent of patients showed poor glycaemic control. It concluded that health care facilities needed improvement in the quality of diabetes care offered and that intervention was needed at the primary care level to improve the risk status of diabetic patients for microvascular and macrovascular diseases.⁴⁴

The CHRC also reported on the Trinidad and Tobago Health Sciences Initiative's (TTHSI) Diabetes Outreach Program that partnered with John Hopkins University School of Medicine in a study within the South-west Regional Health Authority looking at the relationship between patients with diabetes and their current health status. Their main aim was to set priorities for the RHA initiatives for diabetes management with up-to-date surveillance data. 2129 patients in 31 out of 33 health centres were looked at between 2010 and 2011. 50 percent of patients thought their health was either poor or fair, 68 percent saw a health care provider on a regular basis, just 1 percent monitored their blood glucose whilst 33 percent ever recalled having their HbA1c measured. Overall 75 percent of patients had HbA1c greater than 6.5 percent with few patients meeting CHRC guidelines. This study highlighted the need for interventional programs in SWRHA and similar studies to be performed in the other Regional Health Authorities throughout Trinidad and Tobago.⁴⁵

Based on the recommendations of the World Health Organization Commission on Social Determinants of Health (Rio Political Declaration 2011), several countries undertook the commitment to reduce health inequalities. In 2015, a systematic review reported in the West Indian Medical Journal, done by Sobers-Grannum and others,⁴⁶ reviewed 29 full text articles describing the distribution of known risk factors for type 2 diabetes by ethnicity, income, education and occupation. All were quantitative studies and each was assessed for the risk of bias. Although a high risk of bias was found in all the studies, Barbados, Cuba and Trinidad had significant findings for the distribution of diabetes by ethnicity, in that diabetes was more common in Blacks and South Asians (OR 1.87; 95% CI 1.14, 3.05). This review concluded that, published data on the social distribution of risk factors and complications of diabetes in the Caribbean was of poor quality and very limited. It is therefore important to do further studies in the Caribbean to better quantify inequalities in diabetes, that are more robust allowing governments to meet their commitments. In 2015, the West Indian Medical Journal also released an abstract of a systematic review and meta-analysis, in which Sobers-Grannum and others,⁴⁷ reviewed 50 articles from 27 studies which looked at the social distribution of risk factors and complications of diabetes by gender. These were all quantitative studies on type 2 diabetic patients. It was found that being female was a determinant of diabetes in Caribbean. An abstract in the West Indian Medical Journal 2008, looked at differences in attitudes, knowledge and practices by gender in diabetic patients in Guyana. This was a cross-sectional survey of consecutive patients attending clinics at 5 major hospitals in Guyana. Males were less likely to report good lifestyle practices compared to females. However good practices were more likely to be reported by men as it relates to blood glucose monitoring, testing and medical care.⁴⁸

Many barriers to self-care exist and needs to be researched and identified in different populations around the world. Once identified, a framework needs to be established that allows health professional to have interventions that improves health behaviour resulting in improved diabetic self-care management. Such a frame work was developed in Cambridgeshire in a research article published in

the Journal of Diabetes Nursing, 2013, ⁴⁹ called the “Barriers Framework”. In addressing barriers to self-care and diabetes care in general practice, Harwood and others were able to link identified barriers to a potential solution. The intention was to identify barriers at clinical review appointments and then create person-specific management plans. Undertaken as part of a larger study of integrated diabetes care, this research was seen as a new method of conducting yearly reviews which brought about a more holistic approach to treating patients with poor glycaemic control. A questionnaire, either sent previously to the patient, to prevent bias from the nurse’s presence, or face to face was issued looking at education, environmental, psychological, financial and social factors that are associated with poor glycaemic control. If there was a language problem identified, for example, resources were identified for interpreting services.

At the provider level, this framework was particularly useful as it allowed for the better distribution of responsibilities. It allowed for the breakdown of individual tasks associated with each review, bringing clarity and importance to the structure used. This further promoted a longer time for review appointments with shared tasks. This article concluded that a multi-component approach is vital and has the ability to recognise the different patient dynamics at work in primary care practice. This will allow for appropriate tailored solutions and allocation of the necessary resources to improve patient care. The main limitation to this approach is the reluctance of staff to take on the extra work load bringing more frustration to a system with significant time constraints.

Aim

The aim of this study was to determine the patient related factors associated with the overall poor diabetic management of type 2 diabetic patients at the health centres within the Northcentral Regional Health Authority, Trinidad

Objectives

1. To identify the patient related factors associated with elevated HbA1c levels in type 2 diabetic patients at the health centres within the Northcentral Regional Health Authority, Trinidad.
2. To determine the association between identified patient related factors and optimal glycaemic control as measured by HbA1c levels.

Methodology

Study Design

A cross-sectional survey was done of type 2 diabetic patients in the public health system in Northcentral Trinidad. This type of study can provide evidence on health status in a specified group of persons, in a certain location and at a specific point in time.

Location

Two health centres were randomly selected, from each of the three clusters within the Northcentral Regional Health Authority. This was done because there are differences in the socio-demographics in all regions, inclusive of cultural beliefs and practices, and it also reduces sources of selection bias.

Sample size calculation

Based on international studies, a prevalence of 20% was used for patient barriers. Using a sample proportion of 20%, power of 80% and alpha of 5%, a sample size of 246 was calculated using the formula, $\text{sample size} = Z(1-\alpha/2)^2 * P(1-P)/d^2$, for qualitative variables. After giving consideration to an expected participation rate of 80% a final sample size of 295 was calculated.

Population

The study population was all the type 2 diabetic patients attending their chronic disease clinic at the local health centre in their district. Convenience sampling of 25 consecutive diabetic patients, who met the inclusion/exclusion criteria and attended the chronic disease clinics for their usual appointments at each identified health centre over a two month period starting January 1st 2018. Each of the selected health centres was visited on two consecutive weeks so that a total of fifty patients per health centre would be sampled. The dates for data selection was chosen based on the assumption that the approval process from the ethics Committees of the University of the West Indies and the NCRHA would be completed by December 31st 2017.

Inclusion criteria

Patients included in this survey, were adults who gave consent and were 18 years and over with a history of type 2 diabetes. In order to establish that participants were regular clinic patients, each must have attended two or more outpatient clinic appointments within the last 12 months.

Exclusion criteria

Patients with gestational diabetes and no clinic appointment were excluded. Patients with a disability for example, speech or hearing and patients who attended psychiatric outpatient clinics were also excluded since these may prevent adequate communication with the researchers.

Instrument development

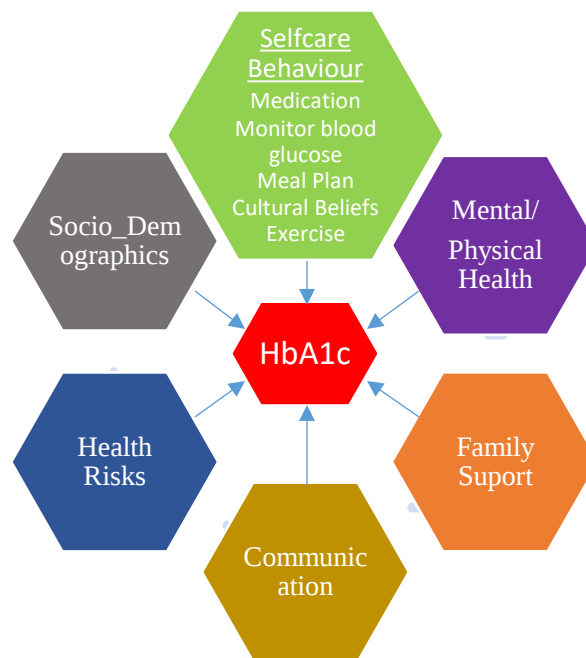
The data collection tool used in this study was adapted from a study by J. M. Daly et al³⁵ entitled “An Assessment of Attitudes, Behaviours and Outcomes of Patients with type 2 Diabetes”. Their questionnaire was developed from an interdisciplinary effort at the University of Iowa to assess self-care behaviours and related barriers. A patient questionnaire entitled “Self-Care Behaviour Survey for Patients with Diabetes” was developed using selected questions from 20 existing diabetes questionnaires in a 2009 study. The final questionnaire used in this study consists of selected questions from the “Self-Care Behaviour Survey for Patients with Diabetes” questionnaire and from another questionnaire entitled “Barriers to Care” adapted from a 1998 study by Simmons and others.³⁸ Simmons et al developed his survey instrument in a study aimed at identifying and qualifying barriers to diabetes care perceived by diabetic patients in New Zealand. In his study, Simmons and others, identified specific barriers to care including psychological factors, knowledge of their current situation, internal physical, community and psycho-social barriers to care. Both questionnaires were later cited by several studies. Permission was sourced and granted by the main authors of the 2 questionnaires used to develop the de novo questionnaire used in this study.

This new questionnaire is based on the conceptual model⁵⁰ for factors influencing HbA1c (our main outcome) as shown in Figure 1.

Conceptual Model

Figure 1: Conceptual Model

Factors Affecting HbA1c



According to the American Diabetes Association, HbA1c as a measure of glycaemic control is a significant predictor of diabetic complications.⁵¹

There are several factors that can independently influence HbA1c levels including, Socio-demographic, Family support, Psychological, Physical, Communication, Health risk and Financial factors. These factors also impact on self-care behaviours which affects HbA1c levels.

Validating Strategy and Pretesting Instrument

After completing the domains of this de novo questionnaire, it was face validated by the department coordinator. The research instrument was then pre-tested with a

small number of 30 patients from the Freeport Health Centre for convenience. Based on responses, only minor modifications were necessary before using it as the data collection tool in this study. It must be noted that even though questions were selected from and placed in similar domains as in these 2 questionnaires, Cronbach's alpha could not be applied to all the domains of the new questionnaire for the following reasons: these domains either had too few questions, open questions, mixture of scales or needed to be reverse scored. Alternatives to Cronbach's alpha include: Average inter-item correlation, Average item-total correlation, Cronbach's alpha, Split-half reliability (adjusted using the Spearman-Brown prophecy formula) and Composite reliability for measuring reliability and validity.⁵²

It is also important to note that the "Self-Care Behaviour Survey for Patients with Diabetes" questionnaire could not be applied in its entirety because it was too long, approximately 130 questions, and seemed complex in certain instances. The "Barrier to Care" questionnaire could not be used by itself either, because of the ambiguity of some questions and some questions were not detailed enough. Both of these would lead to a high non-participation rate resulting in insufficient information respectively.

Demographic data collected via this validated questionnaire included the following: socio-demographic factors inclusive of age, sex, ethnicity, marital status, education levels, income levels, occupation and smoking status. The rest of the questionnaire was divided into sections with considerations given to socio-demographics factors, Family support, Health risks, Potential barriers to diabetes management, Mental/Physical factors, HbA1c measurement, Beliefs, Motivational factors, Use of alternative treatments, Complications of diabetes and Attendance to chronic disease clinics (predictor variables). There is the possibility of recall and information bias since patients will be asked to recall specific information as well as giving their own views. There may also be the problem of unknown confounders that are usually associated with Cross-sectional Studies. Each questionnaire was placed in a sealed envelope in the presence of the patient

and placed in a locked cabinet so that only the researcher had access to this information, in order to ensure confidentiality.

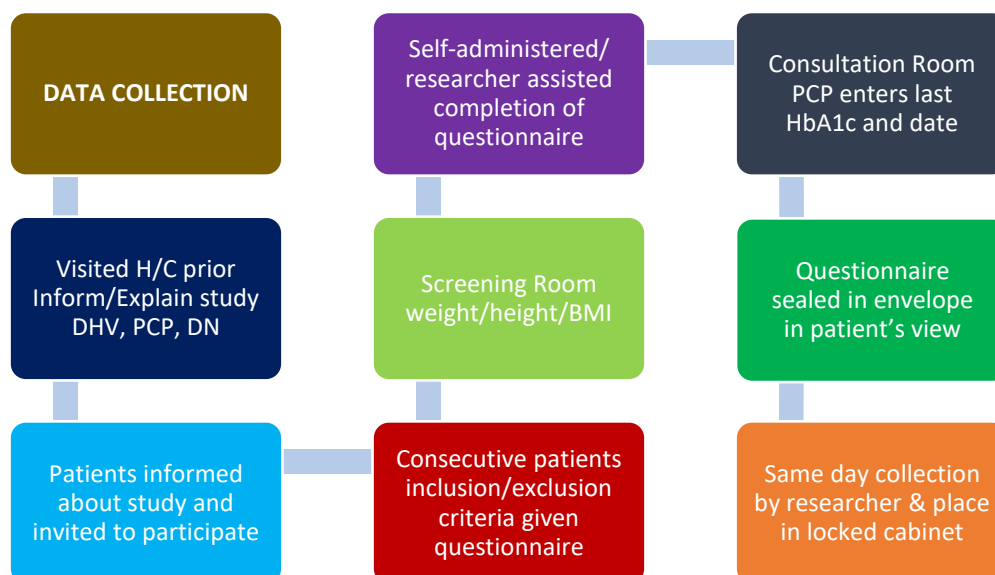
Ethical Considerations

The purpose of this study was to identify patients' personal barriers in achieving optimal diabetes management. This information would be used to improve the patient-centred model of the clinical consultation and will assist physicians in finding innovative ways of overcoming these barriers to self-care behaviours in diabetic patients.

Approvals were obtained from the ethics committees from the Faculty of Medical Sciences University of the West Indies and the NCRHA. Permission was also sought from the CEO NCRHA. At the community level, permission to conduct this survey was also obtained from the respective cluster leaders in the 3 clusters of the NCRHA

Data Collection

Figure 2: Data collection



Each selected health centre was visited on the preceding day of data collection. The purpose of the study was explained to staff inclusive of PCPs, DHVs, Clerks, Nursing Assistants (ENAs) and Patient Care Assistants (PCAs). The investigator arrived the next morning at the start of the chronic disease clinic to greet patients, explain the purpose of the study, inclusion/exclusion criterion and invite patients to participate on a voluntary basis. Patients who were in queue to enter the screening room were given the questionnaire, a consent form was signed and removed from the questionnaire to maintain confidentiality. Patients were given their weight and height by the screening room staff and while waiting for their consultation were able to complete their questionnaire. The PCPs entered the most recent HbA1c and the date it was done on the patient's record. On exiting the consultation room participants were given an envelope to seal the questionnaire, which was collected immediately by the investigator. The investigator assisted those participants who had difficulty with self-administering of the questionnaire, for example, where a literacy problem existed.

Analysis Strategy

The main outcome or dependent variable was HbA1c. Previous research noted that using baseline HbA1c in studies looking at diabetes complications was shown to underestimate the value of HbA1c as a risk factor for diabetic complications.⁵³ The mean HbA1c has been shown to be a better estimator of risk for diabetic complications.⁵³⁻⁵⁵

Descriptive statistics were generated with frequencies and percentages in order to observe general important characteristics of the data set. Analysis of means using the Independent T test for variables with 2 groups and the Analysis of Variance (ANOVA) statistical test was applied to variables with 3 or more groups. To simplify the analysis, most of the questions with an answer of "Don't Know" was changed to 'No' where it was reasonable to do so. Participants were analysed in 2 groups based on length of time since the last recorded HbA1c. The answers to open-ended questions were placed in themes, then categories and assigned value labels under each variable. The Chi-squared test was applied to categorical variable to determine any associations.

Results

Socio-Demographics

A total of 290 subjects were invited to participate in this study, 254 participated in the completion of the survey and 36 refused participation. The calculated response rate was 87.6%. Only 200 (78.7%) participants had recorded HbA1c and these were included in the analysis.

The mean age of subjects was 61.65 years (SD, 10.75). The oldest participant was 87 years, the youngest was 28 years and the median age was 63 years. Females (70.5%) outnumbered males (29.5%) just over 2:1. BMI was calculated for a total of 152 subjects. Most participants (35.5%) were found to be overweight with a BMI in the range 25-29. There were 41 females versus 13 males in this category. Only 41 (27%) participants had a BMI in the range 15-24 and 57 (37.5%) were obese. Age was found to be significantly associated with mean HbA1c in this group.

Table 1: Ethnicity

Ethnicity	Frequency	Percentage
East Indian	109	54.5
African	57	28.5
Mixed (African/East Indian)	14	7.0
Mixed (other)	19	9.5
Chinese	1	0.5
Total	200	100

Table 1 above shows the frequency and percentage of the ethnic composition of participants. There was no significant association found between mean HbA1c and ethnicity.

Most participants (44%) reported being married, 43 (21.5%) were widowed, 31 (15.5%) were single, 19 (9.5%) were divorced or separated and 19 (9.5%) had a common-law or visiting relationship. The reported number of participants residing

alone was 36 (18%). No significant association with mean HbA1c was found in this group.

Table 2 below shows the frequency distribution of the highest level of education received. University or tertiary education was the highest level of education received by participants (8.5%). However, 87 (43.5%) subjects reported primary education as their highest level of education received. There was no significant association with mean HbA1c and education status.

Table 2: Highest level of Education

Highest level of Education	Frequency	Percentage
Primary	87	43.5
Secondary	76	38.0
Vocational training	17	8.5
University/ Tertiary	17	8.5
Other	3	1.5
Total	200	100

Table 3 below shows the current employment status of participants. Of those currently employed 27 (13.5%) had full time jobs working at least 35 hours per week. Retirees formed the largest group, 39%, followed by homemakers 23% and 26 (13%) were disabled and not able to work. Being retired was significantly associated with a lower mean HbA1c.

Table3: Current Employment Status

Current Employment Status	Frequency	Percentage
Full-time, >35hrs	27	13.5
Part-time, <35hrs	10	5.0
Unemployed/ Laid off/ want to work	3	1.5
Unemployed/ not looking for work	8	4.0
Home maker	46	23.0

In school	2	1.0
Retired	78	39.0
Disabled/ not able to work	26	13.0
Total	200	100.0

The reported monthly income (TT dollars) of participants' households demonstrated that 150 (75%) subjects had a monthly household income of < \$5,000; 21.0% had an income of \$5,000-\$9,999; 3.5% had an income of \$10,000-\$14,999 and just 1 participant (0.5%) had an income over \$20,000. 62 (31.0%) participants reported having a diagnosis of type 2 diabetes for > 15 years and represented the largest group. 58 (29.0%) had a 6-10 year history of diabetes, 49 (24.5%) for less than 5 years and 31 (15.5%) were diagnosed 11-15 years ago. The mean HbA1c reported was 8.36% (SD, 2.06) with a range of 4.8%-14%. Just 6.5% of subjects smoke at least one cigarette a day. There were no significant associations with mean HbA1c and income level or length of time of diagnosis with type II diabetes.

Table 4: Communication

Communication	n=200	Frequency	Percentages
Are you always able to understand your diabetic team			
Yes		149	74.5
No		51	25.5
Do you feel 'comfortable' talking with your diabetes team			
Yes		193	96.5
No		7	3.5
Does your diabetes team spend enough time on your diabetes			
Yes		130	60.5
No		70	35

Please describe any other problems that make it difficult for you to keep your clinic appointments		
None	167	83.5
Other health problems	7	3.5
Other duties	4	2.0
Financial problems	2	1.0
Forgot	2	1.0
Work	6	3.0
No transport	11	5.5
Hospital clinics clashing	1	0.5
How could your primary care (family) doctor help you more with your diabetes		
Nothing	121	60.5
Lectures	12	6.0
Shorter appointments	3	1.5
Spend more time	45	22.5
Listen more	9	4.5
Get glucometer	2	1.0
Home visit	1	.5
Get social assistance	5	2.5
See same doctor at each visit	1	.5
Find cure	1	.5

Table 4 above shows the frequency distribution for the domain communication. 25.5% reported that they did not understand the information and instructions given by their diabetic team. 74.5% reported they were able to understand and follow instructions given and approximately 96.5% of participants felt

comfortable with their diabetic team. 35.0% reported not having enough time at the consultation. Although there were several reasons given for not attending the diabetic clinic for example transportation problems, other health issues, and financial problems, 83.5% attended their clinic appointment regularly, 22.5% claim they needed more time at their consultation, 6.0% wanted their primary care physician (PCP) to give more information through lectures, 4.5% wanted their PCP to listen more and 60.5% thought there was nothing more their PCP could do to help them with their diabetes care. There were no significant association between mean HbA1c and barriers to communication.

Table 5: Family support

Family support	Mean	P	Frequency	Percentage
Do others prevent you from looking after your diabetes				
Yes	9.70	0.258	3	1.5
No	8.34		197	98.5
Total			200	100
How much does family/people support you with your DM				
1	8.31	0.527	57	28.5
2	7.81		15	7.5
3	8.81		21	10.5
4	7.89		17	8.5
5	8.47		90	45.0
Total			200	100
How much does family/people know about DM				
1	8.37	0.162	52	26.0
2	7.96		20	10.0
3	9.02		42	21.0
4	7.92		25	12.5

5	8.20	0	61	30.5
Total			200	100
Do others make you feel badly because you have diabetes				
Yes	7.63	0.252	10	5.0
No	8.34		190	95.0
Total			200	100
Do family responsibilities stop you from looking after your diabetes				
Yes	8.75	0.525	11	5.5
No	8.34		189	94.5
Total			200	100

Table 5 above shows the frequency distribution, mean and p values of factors affecting family support. 98.5% of participants claimed that no one prevented them from taking care of their diabetes, 64.0% felt they had adequate family support and just 64.0% of their family had adequate knowledge of diabetes. More than 94% of subjects was able to take care of their diabetes despite family responsibilities. There was no significant association with mean HbA1c and barriers to family support.

Self-care behaviour

Table 6: Use of Medication

Use of Medication	n= 200	Frequency	Percentage
Take tablets to control blood sugar			
Yes		171	85.5
No		29	14.5
Inject insulin to control blood sugar			
Yes		54	27.0
No		146	73.0
Take tablets to control blood pressure			

Yes	162	81.0
No	38	19.0
Take tablets to control Cholesterol		
Yes	132	66.0
No	68	34.0
Describe problems that prevent you from taking meds as recommended		
None	140	70.0
Health problems	7	3.5
Work	5	2.5
Forgot	17	8.5
Unavailability of meds	19	9.5
Fed up	4	2.0
Don't like needles	2	1.0
Normal glucose readings	5	2.5
Alcohol use	1	.5

Table 6 above shows the frequency distribution of medication use. The reported mean HbA1c was $8.36\% \pm 2.06$, most participants 142 (71.0%) were on oral hypoglycaemic agents only, 25 (12.5%) were on insulin only and 14.5% were taking both insulin and oral hypoglycaemic medications and 4.0% took neither insulin nor oral hypoglycaemic medications to control their diabetes. 81.0% of participants took medications for associated hypertension and 66.0% for hypercholesterolaemia. While 70.0% of subjects described no problems with taking their medications, 9.5% did not take medications because it was unavailable at the local health facility, 8.5% forgot and 3.5% did not take their meds because of other health concerns for example alcoholism, fear of hypoglycaemia and 2.5% did not take medications if they thought their glucose level was normal. While taking oral hypoglycaemic agents were significantly

associated with lower mean HbA1c, taking insulin was significantly associated with a higher mean HbA1c.

Table 7: Glucose Monitoring

Glucose Monitoring	n= 200	frequency	Percentage
Do you test your blood sugar			
Yes		154	77.0
No		46	23.0
How often do you test your blood sugar			
At doctor's office		29	14.5
At least once a month		25	12.5
At least once a week		65	32.5
One or more times a day		81	40.5

Table 7 above shows that most participants 154 (77.0%) tested their own blood glucose, but just 40.5% did this one or more times a day. 32.5% tested their blood glucose at least once a week and 14.5% only at the doctor's office. There was however no significant relationship with mean HbA1c.

Table 8: Meal Plan

Meal Plan	n- 254	Frequency	Percentage
Do you follow a healthy appropriate diet for diabetes			
Yes		123	61.5
No		77	38.5
Dietitian recommended diet			
Yes		79	39.5
No		121	60.5
Diabetes Educator recommended diet			
Yes		13	6.5

No	187	93.5
Doctor recommended diet		
Yes	92	46.0
No	108	54.0
Other person recommending diet		
Books	2	1.0
No	192	96.0
TV	2	1.0
Internet	1	.5
Radio	1	.5
Family members	1	.5
Church	1	.5
No one recommended diet		
Yes	37	18.5
No	163	81.5
How well do you follow your meal plan		
0	28	14.0
2	1	.5
3	21	10.5
4	4	2.0
5	84	42.0
6	17	8.5
7	15	7.5
8	21	10.5
9	3	1.5
10	6	3.0

In Table 8 above, 61.5% of the participants claims they usually follow a healthy diabetic diet. 11.0% of participants received dietary information from both the dietitian and doctor, 3% from the diabetic educator and doctor, 19.3% received no dietary information.

Table 9: Exercise

Exercise	Frequency	Percentage
How many days per week you do moderate or vigorous activity		
No days	62	31.0
1 day per week	9	4.5
2 days per week	20	10.0
3 days per week	42	21.0
4 days per week	20	10.0
5 days per week	17	8.5
6 days per week	6	3.0
7 days per week	24	12.0
Total	200	100
Please describe any other factors that may prevent you from exercising		
None	35	17.5
Health problems	68	34.0
Weather	7	3.5
Work	22	11.0
Don't feel like it	58	29.0
Tired	10	5.0
Total	200	100
How many days each week do you check your feet		

Not at all	34	17.0
1-3 days	23	11.5
4-6 days	17	8.5
Every day	126	63.0
Total	200	100

According to American diabetes association, patients with prediabetes or diabetes should have moderate-intensity exercise of 150 minutes per week. This usually translates to about 30 minutes per day for 5 days a week. Table 9 demonstrates 62 (31.0%) participants who reported that they did not exercise and approximately 91 (45.5%) subjects reported exercising less than 5 days a week. 34.0% of persons cited health problems for not exercising while 29.0% said they didn't feel like exercising. 63.0% of participants reported daily examination of their feet. There was no significant association with HbA1c.

Table 10: Cultural Factors

Cultural Factors	Frequency	Percentage
Do you take herbal remedies only to control your diabetes		
Yes	6	3.0
No	194	97.0
Total	200	100
Do you take herbal remedies with your regular diabetes medication to control diabetes		
Yes	48	24.0
No	152	76.0
Total	200	100
Are you ashamed of your diabetes		
Yes	12	6.0

No	188	94.0
Total	200	100
Is your diabetes cured		
Yes	11	5.5
No	147	73.5
Don't know	42	21.0
Total	200	100
Do you agree with your doctor's recommendations about your diabetes		
Rarely	3	1.5
Sometimes	48	24.0
Very often	52	26.0
Always	97	48.5
Total	200	100
Who do you believe is responsible for taking care of your diabetes		
Family		
Yes	39	19.5
No	161	80.5
Total	200	100
Myself		
Yes	188	94.0
No	12	6.0
Total	200	100
Friends		
Yes	5	2.5
No	195	97.5
Total	200	100
Doctor		
Yes	70	35.0

No	130	65.0
Total	200	100
What is more important than looking after your diabetes		
Family		
Yes	44	22.0
No	156	78.0
Total	200	100
Other health conditions		
Yes	31	15.5
No	169	84.5
Total	200	100
Work		
Yes	8	4.0
No	192	96.0
Total	200	100
Having fun		
Yes	8	4.0
No	192	96.0
Total	200	100

Table 10 above shows 6 (3.0%) participants who reported taking only herbal remedies for their diabetes . 48 (24%) took herbal remedies with their regular diabetes medication for their diabetes and 6% felt ashamed of being diabetic. 11 (5.5%) believed their diabetes was cured. 48.5% always agreed with their doctor's recommendations, 26% often agreed and 24.0% sometimes agreed. 94.0% believed that they were responsible for taking care of their own diabetes and was associated with a lower mean HbA1c. 22.0% said that taking care of their family was more important than looking after their own diabetes and 15.5% said their other health condition was more important.

Table 11: Motivation

Motivation	Frequency	Percentage
How motivated are you to improve with each of the following		
a) Following my meal plan as recommended		
1	31	15.5
2	10	5.0
3	69	34.5
4	42	21.0
5	48	24.0
Total	200	100
b) Taking my medications as recommended		
1	6	3.0
2	5	2.5
3	26	13.0
4	34	17.0
5	129	64.5
Total	200	100
c) Exercising regularly		
1	41	20.5
2	20	10.0
3	41	20.5
4	46	23.0
5	52	26.0
Total	200	100
d) Testing my blood sugar as recommended		
1	32	16.0
2	13	6.5

3	41	20.5
4	30	15.0
5	84	42.0
Total	200	100
e) Visiting my doctor as recommended		
1	12	6.0
2	3	1.5
3	12	6.0
4	25	12.5
5	148	74.0
Total	200	100
f) Checking my feet regularly		
1	29	14.5
2	5	2.5
3	23	11.5
4	17	8.5
5	126	63.0
Total	200	100

Most participants (Table 11) did not feel well motivated to follow a meal plan 55.0% (110) or exercise 51.0% (102), but felt very motivated to visit their doctor 86.5% (173), taking their medication 81.5% (163) and monitoring their blood glucose as recommended 57.0% (114). There was however no significant associations found between motivation and mean HbA1c.

Table 12: Health Risk

Health risk	Frequency	Percentage
Do you currently smoke cigarettes regularly?		
Yes	13	6.5
No	187	93.5
Total	200	100
Are you able to exercise as much as you would like		
Yes	90	45.0
No	110	55.0
Total	200	100
Do you feel you know enough about diabetes		
Yes	79	39.5
No	121	60.5
Total	200	100
Do you feel that you are able to look after your own diabetes		
Yes	165	82.5
No	35	17.5
Total	200	100
Do you have enough time to look after your diabetes		
Yes	183	91.5
No	17	8.5
Total	200	100
Do you have any known diabetes complications		
a) Eye problems		
Yes	88	44.0
No	112	56.0

Total	200	100
b) Kidney problems		
Yes	13	6.5
No	187	93.5
Total	200	100
c) Foot problems		
Yes	39	19.5
No	161	80.5
Total	200	100
d) Heart problems		
Yes	24	12.0
No	176	88.0
Total	200	100
e) Stroke		
Yes	18	9.0
No	182	91.0
Total	254	100

6.5% (13) or participants (Table 12) smoke at least one cigarette per day. 55.0% (110) felt they did not exercise as much as they would have liked. 60.5% (121) felt that they did not know enough about diabetes. 82.5% (165) thought they could look after their own diabetes and 91.5% (183) reported having enough time to look after their own diabetes. The most common complication of diabetes reported was eye problems 44.0% (88) followed by foot problems 19.5% (39). Kidney problems 6.5% (13) was the least reported diabetic complication in this survey. There were no significant association with barriers to health risk and mean HbA1c.

Table 13: Mental and Physical Health

Mental and Physical Health	Frequency	Percentage
PHQ9 for Depression		
Minimal Depression	123	61.5
Mild Depression	47	23.5
Moderate Depression	23	11.5
Moderately Severe Depression	5	2.5
Severe Depression	2	1.0
Total	200	100.0
In the last 4 weeks, have you had an anxiety attack - suddenly feeling fear or panic?		
Yes	46	23.0
No	154	77.0
Total	200	100
Over the last 4 weeks, how often have you been bothered by feeling nervous, anxious, on edge, or worrying a lot		
Not at all	100	50.0
Less than 2 weeks	60	30.0
More than 2 weeks	22	11.0
Nearly everyday	18	9.0
Total	200	100.0
Due to physical health- accomplished less than you would like		
Yes	74	37.0
No	126	63.0
Total	200	100
Due to physical health- were limited in the kind of work or other activities		
Yes	95	47.5

No	105	52.5
Total	200	100.0
Due to emotional problems-		
a)accomplished less than you would like		
Yes	72	36.0
No	128	64.0
Total	200	100.0
b)Didn't do work or other activities as carefully as usual		
Yes	87	43.5
No	113	56.5
Total	200	100.0
During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?		
Not at all	70	35.0
Slightly	47	23.5
Moderately	32	16.0
Quite a bit	33	16.5
Extremely	18	9.0
Total	200	100.0
During the past 4 weeks, how much of the time has your physical health problems interfered with your social activities (like visiting with friends, relatives, etc		
None of the time	109	54.5
A little of the time	13	6.5

Some of the time	44	22.0
Most of the time	19	9.5
All of the time	15	7.5
Total	200	100.0

According to the patient health questionnaire (PHQ-9) administered to participants 38.5% (77) are considered depressed (Table 13) with a score >5. This suggested that 15% (30) of participant warranted treatment for depression. 20% of responders reported feeling anxious or on edge and not associated with mean HbA1c while 23.0% reported panic or anxiety attacks which was significantly associated with higher mean HbA1c. 37.0% (74) reported they were unable to accomplish their usual tasks due to their physical health and 47.5% (95) felt they were also limited in other activities. 36% (72) felt their emotional health limited their usual activities but 43.5% (87) felt they didn't do other activities as careful as usual. 41.5% (83) had significant pain interfere with performance of their usual activities and 39% (78) were limited in their social activities due to their physical health.

Differences in participants without recorded HbA1c.

In comparison to participants with recorded HbA1c result, those with no recorded HbA1c result had a mean age of 59.2 years $\pm$ 9.69 years with median age 58.5 years. The youngest was 38 years and oldest 77 years. Females were 63% and males 37%. Most participants 40.0% were overweight with BMI 25-29 and 7.5% were obese, (n=40). East Indians made up 59.3% and Africans 22.2% in an approximate 3:1 ratio. Most participants were married, 40.7%, followed by 25.9% who were single. 24.1% lived alone and most participants had a 6-10 years history of diabetes. Only 7.4% had tertiary level education and most (74.1%) had an income level less than TT\$5,000. Retirees made up 29.6% followed by 22.7% who were fully employed.

There were no differences between those with recorded HbA1c and those without HbA1c for the domains family support, self-care behaviour for (use of medication, blood glucose monitoring, meal plan, exercise and motivation) and health risks. However, differences were present for communication where 50% was always able to understand their diabetic team (vs 74.5% of those with recorded HbA1c); cultural factors where 13% use only herbal remedies to control their diabetes (vs 3% of those with recorded HbA1c) and 20.4% who felt ashamed of their diabetes (vs 6% of those with recorded HbA1c); and mental/physical health where 53.7% were depressed (vs 38.5% of those with recorded HbA1c), with 24.1% (vs 15% of those with recorded HbA1c) needing treatment for depression.

Results of analysis of mean HbA1c using Independent Samples T Test and ANOVA

Tables 14 to 23 show the results for analysis using the Independence Sample T-test for dichotomous variables and Analysis of variance (ANOVA) for variables with 3 or more groups with relevant Post Hoc tests. Both tests were performed to determine which groups were strongly associated with the mean HbA1c. The continuous variable HbA1c was compared with all other variables where $p < 0.05$.

Table 14: Factors associated with Higher mean HbA1c

Factors associated with Higher mean HbA1c (N=200)	P
Age	0.033
Use of Insulin	0.000
Emotional problems	0.020, 0.007
Anxiety	0.038

Table 14 above shows the results of the analysis 200 participants with recorded HbA1c. Factors associated with higher mean HbA1c were: age $p=0.033$, use of insulin $p=0.000$, those experiencing emotional problems in the previous 4 weeks $p=0.020/0.007$, and those experiencing anxiety in the previous 4 weeks $p=0.038$.

Table 15: Factors associated with Lower mean HbA1c

Factors associated with Lower mean HbA1c (N=200)	P
Use of oral hypoglycaemic agents	0.000
Personal responsibility for diabetes care	0.030
Employment status (Retired)	0.002

Table 15 above shows the factors associated with a lower mean HbA1c in 200 participants with recorded HbA1c. These included: use of oral hypoglycaemic agents $p=0.000$, those who took personal responsibility for their diabetes care $p=0.030$, and those who were retired $p=0.002$.

Table 16: Results for PHQ-9 for Depression

PHQ9 for Depression	Valid Percent/Frequency
Valid Minimal Depression	61.5 (123)
Mild Depression	23.5 (47)
Moderate Depression	11.5 (23)
Moderately Severe Depression	2.5 (5)

Severe Depression	1.0 (2)
Total	100.0 (200)

Table 16 above illustrates the results of the Patient Health Questionnaire-9 (PHQ-9) for all participants in this study n= 200. 61.5% of participants had minimal depression and 23.5% had mild depression. Both groups did not require an intervention. Those with moderate depression 11.5%, moderately severe depression 2.5% and severe depression 1.0%, that is, 15% of participants required treatment for depression.

Table 17: Factors associated with Higher Mean HbA1c: Age

<u>Age</u>	N=200	Mean HbA1c	P
25-34	3	8.567	0.033
35-44	11	8.655	
45-54	31	8.695	
55-64	72	8.866	
65-74	64	7.855	
75-84	17	7.448	
85-94	2	6.95	
Total	200	8.36	
Post Hoc Test (LSD)			
55-64 vs 65-74			0.004

Table 17 above shows that there was an association with age and higher mean HbA1c. The statistical test used was ANOVA with a significant association $p=0.033$. The ANOVA test only shows an association between age and mean HbA1c and a Post Hoc test, in this case LSD, was required to determine which group was significant and demonstrated a significant association between the age groups 55-64 and 65-74, $p=0.004$.

Table 18: Factors associated with Higher Mean HbA1c: Use of insulin

Use of Insulin	N=200	Mean HbA1c	P
Yes	54	9.811	0.000
No	146	7.824	
Total	200		

Table 18 above shows that there was a significant association between the use of insulin and higher mean HbA1c. The statistical test used was the Independent Samples T-test for variables with 2 groups, $p=0.000$.

Table 19: Factors associated with Higher Mean HbA1c: Emotional problems

<u>In the past 4 weeks, due to emotional problems</u>	N=200	Mean HbA1c	P
a) Accomplished less than you would like			
Yes	72	8.812	0.020
No	128	8.106	
Total	200		
b) Didn't do work or other activities as carefully as usual			

Yes	87	8.805	0.007
No	113	8.017	
Total	200		

Table 19 shows that there was an association between those with emotional problems and a higher HbA1c. The statistical test used was the Independent Samples T-test for variables with 2 groups. In the past 4 weeks those who accomplished less than they would of liked to due to emotional problems was significantly associated with a higher mean HbA1c, $p= 0.020$. Also, in the past 4 weeks those who didn't do work or other activities as carefully as usual due to emotional problems was associated with a higher mean HbA1c.

Table 20: Factors associated with Higher Mean HbA1c: Anxiety

In the last 4 weeks, have you had an anxiety attack-suddenly feeling fear or panic?	N=200	Mean HbA1c	P
Yes	46	8.913	0.038
No	154	8.195	
Total	200		

Table 20 above shows the relationship between anxiety and mean HbA1c. The statistical test used was the Independent Samples T-test for variables with 2 groups. Those who experienced anxiety attacks or a sudden feeling of fear or panic was significantly associated with a higher mean HbA1c, $p=0.038$. The effect of anxiety on glycaemic control can be further evaluated in a Cross-Sectional study to determine the prevalence of anxiety and assess its impact on glycaemic control.

Table 21: Factors associated with Lower Mean HbA1c: Employment Status

<u>Employment Status</u>	<u>N=200</u>	Mean HbA1c	P
Full-time > 35hrs	27	8.152	0.002
Part-time < 35hrs	10	8.35	
Unemployed/ Laid off/ want to work	3	10.867	
Unemployed/ not looking for work	8	7.7	
Home maker	46	8.876	
In school	2	6.65	
Retired	78	7.811	
Disabled/ not able to work	26	9.362	
Total	200	8.36	
Post Hoc Test (Bonferroni)			
Retired vs Disabled			0.019

Table 21 above shows the association between employment status and mean HbA1c. The statistical test used was ANOVA for variables with 3 or more groups. Employment status was significant associated with a lower mean HbA1c, $p = 0.002$. The Post Hoc Test, Bonferroni, was used and showed that being retired versus being disabled was significantly associated with a lower HbA1c, $p = 0.019$.

Table 22: Factors associated with Lower Mean HbA1c: Use of oral hypoglycaemic agents

Use of oral hypoglycaemic agents.	N=200	Mean HbA1c	P
Yes	171	8.109	0.000
No	29	9.84	
Total	200		

Table 22 above shows that an association exists between use of oral hypoglycaemic agents and HbA1c. The statistical test used was the Independent Samples T- test for variables with 2 groups. Use of oral hypoglycaemic agents was associated with a lower mean HbA1c, $p=0.000$.

Table 23: Factors associated with Lower Mean HbA1c: Personal responsibility for diabetes care.

Who do you believe is responsible for taking care of your diabetes? - Myself	N=200	Mean HbA1c	P
Yes	188	8.28	0.030
No	12	9.61	
Total	200		

Table 23 above shows that most participants believed that they were responsible for their own diabetes care. The statistical test used was the Independent Samples

T- test for variables with 2 groups. The belief that participants were responsible for their own diabetes care was associated with a lower mean HbA1c, $p=0.030$.

Discussion

The intention of this study was to determine the patient related factors associated with glycaemic control and to determine the association between these factors and optimal glycaemic control as measured by HbA1c levels.

In this study, a de novo survey tool was used to determine patient related factors associated with glycaemic control in type 2 diabetic patients in Trinidad. This survey tool was developed from 2 other validated survey tools with the advantage that it was administered in 15-20 minutes. Patient related factors were determined based on the association with the mean HbA1c.

Table 24: Comparison of Findings

Barriers to diabetes care reported by previous studies	Factors associated with Higher mean HbA1c in this study
Depression	Age (55-64 age group)
Strictness of regimen	Use of insulin
Cost	Emotional problems
Lack of motivation	Anxiety
Education	
Communication	
Diet	Factors associated with lower mean HbA1c in this study
Exercise	Use of oral hypoglycaemic agents
Smoking	Personal responsibility for diabetes care
Use of alternative medicine	Being retired
Factors associated with lower HbA1c in previous studies	

Married, Taking medications, Blood glucose testing	
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The above table compares the barriers and factors leading to higher or lower mean HbA1c values in previous studies and this study. Reported barriers in previous studies included: depression, strictness of regimen, cost, lack of motivation, education, communication, diet, exercise, smoking and use of alternative medicine. In this study, age (55-64 age group), use of insulin, emotional problems and anxiety were associated with higher mean HbA1c values. In previous studies, being married, taking medications and blood glucose testing were associated with lower HbA1c values. Use of oral hypoglycaemic agents, taking personal responsibility for diabetes care and being retired were associated with lower mean HbA1c values in this study.

Table 25: Barriers to diabetes care reported by previous studies and considered in this study

Barriers to diabetes care reported by previous studies	This Study (N=200) P-values
Depression	0.297
Strictness of regimen	Unknown
Cost	0.083
Lack of motivation	0.544
Education	0.901
Communication	0.392

Diet	0.063
Exercise	0.519
Smoking	0.990
Use of alternative medicine	0.088

This study was able to look at all previous barriers with the exception of strictness of regimen, as shown in the above table ($p > 0.05$) and did not find similarities. However, factors associated with higher mean HbA1c represented new findings in this study. Similarly, reported factors to lower HbA1c values in previous studies were not found in this study. Factors associated with lower mean HbA1c also represented new findings in this study.

The domains showing significant association with mean HbA1c in this study included:

- 1) Socio-demographic, the age group 55-64 was associated with a higher mean HbA1c and may be explained by increased job responsibility, little to no time for exercise or diet and missed medical appointments. Being retired was associated with a lower mean HbA1c. This may be explained by comorbidities, fear of mortality, living with relatives and more free time to attend clinic appointments.
- 2) Self-care behaviour, use of insulin was associated with a higher mean HbA1c which may be explained by the tendency for patients to hold off insulin therapy for too long, sometimes until diabetic complications arise, in contrast, the use of oral hypoglycaemic agents was associated with a lower mean HbA1c which may be explained by better compliance with oral medications. Participants who believed that diabetes was their own responsibility was associated with a lower mean HbA1c. This may be explained by participants having better life style choices to include exercise, diet, and blood glucose monitoring.

3) Mental and physical health, this study was able to highlight the high prevalence of depression in type 2 diabetic patients. Although not seen as a significant barrier to diabetes management in this study, physicians need to be acutely aware of depression in patients at their routine clinic appointments and refer for specialist care or commence treatment when required. Patients who were faced with emotional problems had difficulty in achieving their daily task or didn't complete tasks as carefully as usual was associated with higher mean HbA1c. Poor lifestyle choices and lack of self-care may explain these findings as well as the finding that having anxiety symptoms was similarly associated with higher mean HbA1c. This further highlights the need for screening diabetic patients for both depression and anxiety.

The other domains including health risks, communication and family support were not significantly associated with mean HbA1c values. Mental and physical health, was the most common domain, significantly associated with mean HbA1c.

The issue of timely HbA1c at routine clinic visits needs to be addressed within the NCRHA since most patients did not have HbA1c within a 6 month period. This problem may be partially due to the long clinic appointments given to patients (usually 4-6 months appointments) and patients missing their appointment.

Most participants in this study were compliant with their clinic appointment and therefore, expected to have HbA1c <7.0%. This however was not the case and may be due to patient barriers, health-care professional barriers, institutional barriers or a combination of these. Only after a thorough analysis and treatment of patient barriers/factors, should consideration be given to other barriers/factors to diabetes care based on elevated HbA1c values.

The majority of patients in this study were found to be either overweight or obese and many researchers have found associations with poorer glycaemic control, uncontrolled blood pressure and poorer health outcomes. This was however, not demonstrated in this study. Larger numbers of patients with HbA1c within a 3-6 months period may be needed.

Internationally, Simmons and others³⁰ reported in a New Zealand study that psychological barrier was the most common reported barrier. In this study emotional problems and anxiety/panic attacks were significantly associated with higher mean HbA1c. Daly et al³⁵, reported in a United States study that depression was significantly associated with higher HbA1c, which was similar in a European study³⁹, but was not demonstrated locally. There was however a high percentage of patients found to be depressed according to PHQ-9 scores. While lack of motivation, education, presence of co-morbidities, cost and shift work were the main barriers found by Brown and others⁴³, in a Canadian study, there were no similar barriers/factors found locally even though most patients were not motivated to follow a meal plan or exercise, 55.9% and 56.3% (n=254) respectively.

Regionally, Education was a significant barrier in Guyana⁴⁸ (based on gender differences) and in Jamaican⁴² studies, this was not found locally and gender was not significantly associated with mean HbA1c. There was no association found between gender and patients who thought they knew enough about diabetes ($\chi^2 = 0.329$, df=1, p= 0.567). In a Barbados study by Adams and Carter⁵⁶, barriers found included diet, exercise, taking medication and stress, however, the use of insulin was associated with higher mean HbA1c locally.

Although there were no similar local studies done, Islam et al⁵⁷, in a 2013 study looked at barriers to foot care and noted that the use of alternative medicine was a significant barrier. Use of alternate therapy in relation to herbal therapy was not demonstrated locally. In this study, foot problems was the second most common diabetes complication reported, 21.7% (n= 254). One of the main reported barriers to insulin therapy reported by Beneby et al⁴⁰, in 2015 was communication. In this study, communication did not feature as a significant barrier/factor to diabetes management, but there is the need for a well-structured consultation at routine clinic appointments which should clearly address specific patient issues.

Impact of this study

This study is the first of its kind and has added relevant national information in relation to patient related factors affecting diabetes treatment in Trinidad.

Implementation of feasible barrier interventional programs at revisit appointments for the most vulnerable demographic groups will likely see improvement in diabetes treatment in Trinidad and Tobago which can be applied to our Caribbean neighbours.

Patient's interest and motivation in both participation in treatment/intervention and future research will bring a new energy to self-care management. This will stimulate further local and regional research which will add to and support evidence based management.

Strengths of study

The strength of this study was demonstrated firstly by the reflected ethnic and cultural composition within the geographic region served by the RHA. Secondly, there was an improved patients' interest in participating in research and a concern about improving their HbA1c. Thirdly, this study added new information to local data which can be used as a baseline for future research.

Limitations

In the absence of a patient friendly well validated tool looking at the major barrier domains that arose from the literature review, a de novo survey was created.

While this tool was unable to demonstrate associations between these domains and HbA1c, several significant patient related predictors of glycaemic control were found. Validation of an ideal tool to measure the various barrier domains was beyond the scope of this current work.

This study was not able to evaluate the Socio-Demographics of the non-responders which may be significantly different from responders and affect the accuracy of the findings. The samples size used for analysis of mean HbA1c was small and may affect the reported results.

This was a Cross-sectional study and which looks at one point in time. Further research following a cohort of patients may reveal new information necessary for the evolution of diabetes management in Trinidad and Tobago.

Information from private institutions was unavailable and outside the remit of this study. Hence, there may be significantly undetected, important patient factors amongst the working class. It is noted that the mean age of participants was 61.1 years $\pm$ 10.56, this implies that a large section of younger adults who also make up the working class was not investigated and results may be skewed.

Most of the participants in this study did not have current HbA1c and this may have affected the reported patient factors affecting diabetes care. This was because of the financial constraints placed on all RHAs in a fiscal depressed local economy at the time of this study.

The sample size used at each health centre was the same (50 participants). This may have impacted the results since the clinic sizes differed almost twice or three times in the larger health centres as compared to the smaller health centres. Proportional representation would have been the preferred method.

Bias and challenges

This was a Cross-sectional study and was not without bias or challenges. Convenience sampling was done and likely to result in Selection Bias since there may be patients who missed their clinic appointments and the fixed number of invited participants may not be representative of the overall population. In an attempt to minimise this several health centres were randomly selected within the 3 clusters of the NCRHA.

The survey tool consisted of 68 questions, although it was pretested and pilot tested, literacy problems increased the rate of researcher-assisted administration and likely to result in interviewer bias and the Hawthorne effect, where patients being investigated give a response that may be different when the questionnaire is only self-administered.

There were several challenges in putting together the survey tool. Neither of the 2 questionnaires used in designing the survey tool used in this study could be used in its entirety. The questionnaire by Daly et al, was too long and some of the questions in the survey tool by Simmons and others seem ambiguous or unclear. Cronbach's alpha could not be calculated for certain domains and further research is required to determine the validity of the survey tool.

The main challenge of this study was getting a recent HbA1c within the last 3 months. Attempts were made to reduce this problem by liaising with the administrative PCPII in each cluster, in providing the kits for point of care testing. There was some success in this regard initially but later-on met with financial challenges due to a recession in the local economy.

Recommendations

In the fight against diabetes mellitus and its complication, it is very important to be able to determine what barriers/factors patients are faced with on a personal basis since much of the management of this lifestyle problem is self-care based. This de novo questionnaire can be used in its present form or evolve into a version that can be easily administered at the diabetic and chronic disease clinics at all health centres within each of the RHAs in Trinidad and Tobago in order to determine the predominant patient barriers/factors present. Even though most selected participants were compliant with their clinic appointment, their HbA1c values were elevated, suggesting personal barriers/factors may exist and require an intervention.

The relevant stake holders should be brought together to develop new feasible programs that can be implemented at revisit appointments. Patients usually spend a long time waiting to see the PCP at clinics and this period can be put to better use with these interventions. This will of course require more trained personnel or a more efficient use of existing personnel.

The social support services can be revisited and mandated to follow up with patients at their homes. Since most patients were seen every 6 months, patients were likely to become complacent with diet, exercise, medications, home

monitoring, resulting in social issues like disabilities and loss of employment which could be addressed by home visits.

All health centres or DHFs should be equipped to provide point of care HbA1c results, this will provide up to date results in real time which can be used to monitor progress of patients. Follow up research in the form of RCTs can be used to determine the effectiveness of these programs and interventions. This will likely lead to an evolution in diabetes treatment in Trinidad and Tobago that will positively impact patient's knowledge, attitude and self-care behaviours.

It is hoped that these recommendations can be piloted within one of the RHAs and become part of the national guidelines in diabetes management. The impact will be likely seen in the medium to long term in reduction in diabetes related complications, improved patient wellbeing and reduced net fiscal expenditure.

Conclusion

This study was able to uncover significant factors affecting mean HbA1c including that of: age, use of insulin, emotional problems, anxiety, use of oral hypoglycaemic agents, being retired and diabetes self-care.

In order to overcome some of these challenges in the presence of a diverse ethnic, religious and cultural back ground, it requires firstly re-training of health-care professionals in educating and counselling of patients followed by barrier oriented interventional programs.

Research Budget

Table 26: Budget

Item	Cost per unit	Required number of items	Total cost
Questionnaire	$12 \times 0.5 = \$6.00$	320	$320 \times \$6.00 = \1920.00
Printing final report	\$45.00	2	\$90.00
Binding final report	\$40.00	2	$2 \times \$40.00 = \80.00
Transportation	\$960.00	-	\$960.00
Miscellaneous	\$900.00	-	\$900.00
Total Cost			\$3,950.00

Research Timeline

Table 27: Research Timeline

STAGE	WORK DONE	DATE OF COMPLETION
Preparation of questionnaire	Validation of questionnaire	Nov-17
Pre-testing questionnaire	Minor changes to questionnaire, printing	Nov-17
Ethical approval	Approval from ethics committees – UWI, NCRHA	Jan-18
Preparation for data collection	Random selection of health centres, informing/training	Jan-18
Data collection	Collection and data entry into SPSS	Jan 02 nd – Mar 12 th , 2018
Data analysis	Complete data entry and apply statistical tests using SPSS	Mar-18
Present results	Review with supervisor	Mar-18
Draft of results, discussion, conclusion	Review with supervisor	Mar-18
Final draft of project	Review with supervisor	Mar 31 st , 2018
	Submittal of final document	April 6 th , 2018
Presentation of study to panel	Preparation of power point presentation	May 31, 2018

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Appendix 1

	
THE UNIVERSITY OF THE WEST INDIES ST. AUGUSTINE, TRINIDAD AND TOBAGO, WEST INDIES CAMPUS ETHICS COMMITTEE CONSENT TO PARTICIPATE IN RESEARCH Phone: 645-3232 Ext: 5021 Email: campusethics@sta.uwi.edu	

Complete Protocol Title	Patients' personal barriers in the management of type II diabetes in Trinidad
Principal Investigator	Dr Rohan Maharaj
Co-Investigators	Dr Veykash Ramlogan
Research Site(s)	Primary care health centres within the Northwest, Northcentral, Eastern and Southwest Regional Health Authorities
Sponsors	Not applicable

Why is this research being done?

The researcher, Dr Veykash Ramlogan, is a student of the University of the West Indies and is enrolled in the Doctorate Family Medicine (DM). Dr Ramlogan is conducting research at your health centre to find out what are the personal barriers you are faced with in the management of your diabetes.

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

The questionnaire can be completed in 10-15 minutes and each participant is required to complete just one (1) survey.

What will happen to me?

At your routine chronic disease clinic, you would be invited to participate in this study. This is completely voluntary and you would be asked to complete a questionnaire. You may ask for assistance if needed. All questions can be easily answered from your memory. You would not be subjected to medical experiments or procedures.

What is in it for me?

You would be able to determine the personal barriers that are preventing you from meeting your therapeutic goals. The information gathered here will allow your diabetic team to tailor each of your clinic visits to your specific needs with the aim to improve your diabetes care.

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

Nothing. participation is voluntary and there would be no consequences if you dropped out. You can continue to access health care just like you did in the past.

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

You are responsible for accurate information and complete all questions in the survey.

What if I get hurt in the study?

There are no medical procedures to be performed on you and therefore no harm can come 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

This document was approved by
Campus Ethics Committee on:

January 3 2018

By Chairman:

Sarfo

This document expires on:

January 2 2019



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 from 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:

By signing this document, I agree that I have read 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:

Patients' personal barriers in the management of type II diabetes in Trinidad

Investigators:

Dr Rohan Maharaj, Dr Veykash Ramlogan

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?

Only the researchers.

How long will the investigators use and share my information?

The Study will be completed by 30th June, 2018.

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

You have the right to discontinue participation at any time and the questionnaire will be destroyed.

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

Yes

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.

Appendix 2



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: campusetics@sta.uwi.edu

January 3 2018

Dr. Rohan Maharaj (Veykash Ramlogan)
 Department of Para-Clinical Sciences
 Faculty of Medical Sciences
 Email: rohan.maharaj@sta.uwi.edu; vramlogan321@gmail.com

Dear Dr. Maharaj

Ref: CEC391/12/17
 Patient's personal barriers in the management of Diabetes Mellitus in health centres in Trinidad.

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
 Campus Ethics Committee

/tf

Appendix 3

QUESTIONNAIRE

_____ **Health Centre**

Instructions:

Please tick (✓) the answer of your choice or write it in the spaces provided.

Demographics

1. Please state your **age in**

years _____

2. Gender ☐ Male

☐ Female

3. Please state your **Weight** _____ (kg) and **Height**

_____ (cm)

4. What is your **ethnic**

origin/race?

☐ East Indian ☐ African ☐ Mixed (African/East Indian)

☐ Mixed (other) ☐ White/Caucasian

☐ Chinese ☐ Other _____

5. What is your marital status?

☐ Single ☐ Married ☐ Common-law/Visiting

☐ Widowed ☐ Separated/Divorced

6. Do you live alone?

☐ Yes ☐ No

7. Highest completed Education Level?

☐ Primary ☐ Secondary ☐ Vocational training (Plumbing, electrical, etc.)

☐ University/Tertiary ☐ Other _____

8. Income Level per month?

☐ \$0-\$4,999 ☐ \$5,000-\$9,999 ☐ \$10,000-\$14,999

☐ \$15,000-\$19,999 ☐ \$20,000 and over ☐ Social welfare assistance

9. How many years are you diabetic?

☐ 0-5 ☐ 6-10 ☐ 11-15 ☐ More than 15 years

10. Do you currently smoke cigarettes regularly? (At least one per day)

☐ Yes ☐ No

11. Please state the **date** and **result** of your most recent glycosylated haemoglobin (HbA1c). You can ask your doctor if you can't remember

Date (mm/yy) _____

Result _____ (%)

12. Which of the following best describes your **current** employment status?

- | | |
|--|--|
| ☐ Working full-time, 35 hours or more a week | ☐ In school |
| ☐ Working part-time, less than 35 hours a week | ☐ Retired |
| ☐ Unemployed or laid off and looking for work
able to work | ☐ Disabled, not |
| ☐ Unemployed and not looking for work | ☐ Other |

☐ Homemaker

The next set of questions is about your diet.

13. Do you feel you are able to completely follow a healthy diet **appropriate**

for people with diabetes?

☐ Yes ☐ No ☐ Don't know

14. Which of the following health care professionals have made recommendations about your diet? (Select all that apply)

☐ Dietitian ☐ Diabetes Educator ☐ Doctor

☐ Other _____ ☐ None

15. On a scale from 0 (not at all) to 10 (perfectly), how well do you follow your meal plan? _____

0 Not at all-----5 Half of the meals in a week-----10 All the meals in a week

The next set of questions is about your diabetes medications.

Do you (please tick the relevant box):

16. Take tablets to control your blood sugar?

☐ Yes ☐ No ☐ Don't know

17. Inject insulin to help control your blood sugar?

☐ Yes ☐ No ☐ Don't know

18. Take tablets to control high blood pressure?

☐ Yes ☐ No ☐ Don't know

19. Take tablets to help control your cholesterol?

☐ Yes ☐ No ☐ Don't know

20. Take herbal remedies only to control your diabetes?

☐ Yes ☐ No ☐ Don't know

21. Take herbal remedies with your regular diabetes medication to control your diabetes?

☐ Yes ☐ No ☐ Don't know

22. Please describe any problems that may prevent you from taking your medications as recommended.

The following questions have to do with the activities you do on a usual basis.

23. Do you feel you are able to exercise as much as you would like to?

☐ Yes ☐ No ☐ Don't know

24. How many days per week do you do moderate or vigorous activities for at least 10 minutes such as running, aerobics, or anything else that causes large increases in breathing and heart rate?

☐ 1 day per week

☐ 2 days per week

☐ 3 days/w

☐ 4 days per week

☐ 5 days per week

☐ 6 days/w

☐ 7 days per week

25. Please describe any other factors that may prevent you from exercising.

The next set of questions is about the test you do to monitor your blood sugar.

26. Do you test your own blood sugar? (If not tested in the last month please say no) ☐ Yes ☐ No

27. How often do you test your blood sugar? (Select one)

- ☐ Usually one or more times a day
- ☐ Usually at least once a week
- ☐ Usually at least once a month
- ☐ Only at the doctor's office

The next set of questions is about other factors that may influence your diabetes.

28. Do you feel that you know enough about your diabetes?

☐ Yes ☐ No ☐ Don't know

29. How many days **each week** do you check your feet?

☐ Every day ☐ 1-3 days ☐ 4-6 days ☐ Not at all

30. Do others prevent you from looking after your diabetes?

☐ Yes ☐ No ☐ Don't know

How much does your family or the people that are closest to you: (CIRCLE YOUR ANSWER AT RIGHT) Non -----A lot
1-----5

31. Provide help and support with your diabetes 1 2 3 4 5

32. Know about diabetes 1 2 3 4 5

33. Do you feel others make you feel badly because you have diabetes?

☐ Yes ☐ No ☐ Don't know

34. Is your family helping you to look after your diabetes?

☐ Yes ☐ No ☐ Don't know

35. Do family responsibilities stop you from looking after your diabetes?

☐ Yes ☐ No ☐ Don't know

36. Do you feel that you are able to look after your own diabetes?

☐ Yes ☐ No ☐ Don't know

37. Do you have enough time to look after your diabetes?

☐ Yes ☐ No ☐ Don't know

38. How **motivated** are you to improve with each of the following:

Not Motivated --- Extremely Motivated

(CIRCLE YOUR ANSWER TO THE RIGHT)

1 5

a. Following my meal plan as recommended

1 2 3 4 5

b. Taking my medications as recommended

1 2 3 4 5

c. Exercising regularly

1 2 3 4 5

d. Testing my blood sugar as recommended

1 2 3 4 5

e. Visiting my doctor as recommended

1 2 3 4 5

f. Checking my feet regularly

1 2 3 4 5

39. Are you ashamed of your diabetes?

☐ Yes ☐ No ☐ Don't know

40. Is your diabetes cured?

☐ Yes ☐ No ☐ Don't know

The next set of questions is about your health care visits.

41. Are you always able to understand the information and instructions given to you by your diabetes team?

☐ Yes ☐ No ☐ Don't know

42. Do you feel 'comfortable' talking with your diabetes team?

☐ Yes ☐ No

43. Does your diabetes team spend enough time on your diabetes?

☐ Yes ☐ No

44. Where do you receive most of your diabetes treatment?

☐ Private doctor ☐ Health centre ☐ Hospital ☐ Other_____

45. Please describe any other problems that make it difficult for you to keep your clinic appointments with your primary care (family) doctor for your diabetes.

46. Do you agree with your doctor's recommendations about your diabetes?

☐ Never ☐ Rarely ☐ Sometimes ☐ Very Often ☐ Always

47. How could your primary care (family) doctor help you more with your diabetes?

48. Who do you believe is responsible for taking care of your diabetes? (Please tick all that you feel apply)

☐ Family ☐ Myself ☐ Friends ☐ Doctor ☐ Other_____

49. What is more important than looking after your diabetes (please tick one or more)?

- ☐ Family
- ☐ Other health conditions
- ☐ Work
- ☐ Having fun
- ☐ Nothing
- ☐ Other_____

The next set of questions is about your general physical and mental health.

50. Do you have any known diabetes complications? Please tick the following boxes to show which of these you have:

- ☐ Eye Problems
- ☐ Kidney Problems
- ☐ Foot Problems
- ☐ Heart Problems
- ☐ Stroke
- ☐ None

51. **Over the last 2 weeks**, how often have you been bothered by little interest or pleasure in doing things?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

52. **Over the last 2 weeks**, how often have you been bothered by feeling down, depressed, or hopeless?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

53. **Over the last 2 weeks**, how often have you been bothered by trouble falling or staying asleep, or sleeping too much?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

54. **Over the last 2 weeks**, how often have you been bothered by feeling tired or having little energy?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

55. **Over the last 2 weeks**, how often have you been bothered by poor appetite or overeating?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

56. **Over the last 2 weeks**, how often have you been bothered by feeling bad about yourself, or that you are a failure, or have let yourself or your family down?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

57. **Over the last 2 weeks**, how often have you been bothered by trouble concentrating on things, such as reading the newspaper or watching television?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

58. **Over the last 2 weeks**, how often have you been bothered by moving or speaking so slowly that other people could have noticed? Or the opposite-being so fidgety or restless that you have been moving around a lot more than usual?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

59. **Over the last 2 weeks**, how often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way?

- ☐ Not at all
- ☐ Several days
- ☐ More than half the days
- ☐ Nearly everyday

60. **In the last 4 weeks**, have you had an anxiety attack-suddenly feeling fear or panic? ☐Yes ☐No

61. **Over the last 4 weeks**, how often have you been bothered by feeling nervous, anxious, on edge, or worrying a lot?

- ☐Not at all
- ☐Less than 2 weeks
- ☐More than 2 weeks
- ☐Nearly everyday

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

62. **Accomplished less** than you would like ☐ Yes ☐ No

63. Were limited in the **kind** of work or other activities ☐ Yes ☐ No

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious) ?

64. **Accomplished less** than you would like ☐ Yes ☐ No

65. Didn't do work or other activities as **carefully** as usual. ☐ Yes ☐ No

66. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all ☐

Slightly..... ☐

Moderately..... ☐

Quite a bit..... ☐

Extremely..... ☐

67. During the **past 4 weeks**, how much of the time has your **physical health problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

☐ All of the time

☐ Most of the time

☐ Some of the time

☐ A little of the time

☐ None of the time

68. Do you require financial assistance to manage your diabetes?

☐ Yes ☐ No ☐ Don't know

I wish to thank you for your participation in this survey