DIAGNOSTIC PERFORMANCE OF THE FINNISH DIABETES RISK SCORE FOR UNDIAGNOSED DYSGLYCAEMIA IN WESTERN KENYA

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SM/PGM/03/18

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DECLARATION

Declaration by the Candidate

This research is my original work and has not been presented before for another degree in any other University. No part of this thesis may be reproduced without the prior written permission of the author and/or Moi University.

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DEDICATION

This research study is dedicated to my dear wife who has been my pillar and has been with me every step of the way, encouraging me to keep working even when circumstances seemed unfavourable for work.

I also dedicate this research study to my family which has always seen the potential in me and pushed me to strive to achieve higher goals.

Finally, I especially dedicate this research study to the late Dr Ignatius Muguiyi Muturi, my loving dad, friend, and mentor. May your soul last in everlasting peace.

ABSTRACT

Background: In Kenya, the screening of dysglycaemic states, such as prediabetes and diabetes, is conventionally done through blood glucose testing, which is often impractical to implement. The Finnish Diabetes Risk Score (FINDRISC), an easy-to-use, valid, and freely available non-invasive pre-screening tool has the potential to improve Kenya's dysglycaemia screening strategy as part of the multistage screening strategy recommended by the WHO for resource-constrained settings. FINDRISC is a one-page questionnaire containing eight questions of non-invasively measured risk factors for dysglycaemia that was derived from a ten-year prospective study for identification of individuals with a high risk for developing diabetes among the Finnish population and has been validated in many populations. The diagnostic performance of FINDRISC in a pragmatic setting in Kenya remains unknown, hence the need for this study.

Objectives: To evaluate the diagnostic performance of FINSRISC and determine its optimal cut-off scores for detecting adults with undiagnosed dysglycaemia in a rural population of Western Kenya.

Methods: This was a cross sectional study conducted among 382 participants within Trans-Nzoia county of Western Kenya between November 2020 and February 2021. Participants were enrolled via simple random sampling and stratified according to age group. Data was collected using an adopted FINDRISC questionnaire and subsequently participants were tested using OGTT, which was the gold standard test to determine glycaemic status. Continuous variables were presented as mean (SD or 95% CI), while categorical variables were presented as proportions. Comparisons between normally distributed continuous variables were performed using Student's t-test, while associations between categorical variables were done using Fisher's exact test. Measures of diagnostic accuracy (sensitivity, specificity, positive predictive value [PPV] and negative predictive value [NPV]) were calculated for various FINDRISC cut-off points for both prediabetes and diabetes using OGTT results as the gold standard test for dysglycaemia. Discrimination was determined by calculating the area under the receiver operating characteristics curve (AUROC).

Results: The study population was predominantly (92.9%) rural. The mean age was 45.5 years, and majority of the participants (68%) were female. The overall prevalence of undiagnosed diabetes and prediabetes was 3.9% (95% CI 1.97-5.88) and 7.9% (95% CI 5.14-10.56) respectively. Using OGTT as the gold standard test for dysglycaemia, FINDRISC detected undiagnosed diabetes with 67% (95% CI 38-88) sensitivity and 93% (95% CI 90-96) specificity at a cut-off score of ≥14, AUROC 0.80 (95% CI 0.75-0.84). It detected undiagnosed prediabetes with 57% (95% CI 37-75) sensitivity and 75% (95% CI 70-80) specificity at a cut-off score of ≥10, AUROC 0.64 (95% CI 0.59-0.69). FINDRISC detected both prediabetes and diabetes with 60% (95% CI 44-74) sensitivity and 77% (95% CI 72-81) specificity at an optimal cut-off point of ≥10, AUROC 0.69 (95% CI 0.64-0.74). It demonstrated a low PPV (26% [95% CI 20-32]) but a high NPV (94% [95% CI 90-95]) for dysglycaemia.

Conclusion: FINDRISC had a high NPV for dysglycaemia at an optimal cut-off score of ≥10.

Recommendation: FINDRISC should be used as a pre-screening tool, and diagnostic laboratory testing for dysglycaemia limited to individuals with a score of ≥10.

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LIST OF ABBREVIATIONS

2-hr PG 2-hour Plasma Glucose

ADA American Diabetes Association

AMPATH Academic Model Providing Access to Healthcare

AUROC Area Under the Receiver Operating Characteristics

BMI Body Mass Index

BP Blood Pressure

CHV Community health volunteer

CHP Community Health Promoter

CKD Chronic Kidney Disease

DBP Diastolic Blood Pressure

DCCT Diabetes Control and Complications Trial

FANTA The Food and Nutrition Technical Assistance Project

FINDRISC Finnish Diabetes Risk Score

FPG Fasting Plasma Glucose

HbA1C (A1C) Glycated Haemoglobin

IDF International Diabetes Federation

IFG Impaired Fasting Glucose

IGT Impaired Glucose Tolerance

IREC	Institutional Research & Ethics Committee
NCD	Non-Communicable Disease
NGSP	National Glycohemoglobin Standardization Program
NGT	Normal Glucose Tolerance
NHIF	National Hospital Insurance Fund
NPV	Negative Predictive Value
OGTT	Oral Glucose Tolerance Test
PIC4C	Primary Health Integrated Care Project for Chronic Conditions
PPV	Positive Predictive Value
RA	Research Assistant
SBP	Systolic Blood Pressure
SSA	Sub-Saharan Africa
WC	Waist Circumference
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERMS

Term	Definition
Body Mass Index (BMI)	A measure of **obesity**, calculated as weight in kilograms divided by height in metres squared (kg/m2) (MOH, 2018a). Three categories were defined: • Normal: BMI <25 kg/m2 • Overweight: BMI 25 – 29.9 kg/m2 • Obesity: BMI ≥ 30 kg/m2
Diabetes mellitus (diabetes)	Using OGTT, at least one of the following: • FPG: ≥7.0 mmol/l • 2-hour PG: ≥11.1 mmol/l
Diagnostic accuracy	Ability of a test to detect a condition when it is present and detect the absence of a condition when it is absent.
Diagnostic performance	Diagnostic accuracy and discriminatory ability (discrimination)
Discriminatory ability (discrimination)	Ability of a test to distinguish between a normal and diseased state.
Dysglycaemia	A state of hyperglycaemia; either prediabetes or diabetes.
Employment status	
Formally employed	Participants receiving majority of their income from a salary or wages.
Self-employed	Participants receiving majority of their income from businesses that they own, including small businesses and farming for profit purposes.
Unemployed	Participants who are neither salaried nor own businesses (not working for income purposes).
Hyperglycaemia	High blood glucose.
Hypertension	Either systolic blood pressure (SBP) ≥140 mmHg or diastolic blood pressure (DBP) ≥90 mmHg, or both (MOH, 2018b).
Negative Predictive Value (NPV)	The probability that participants with a negative test result do not have disease.
Normoglycaemia	Normal blood glucose
Optimal cut-off score	A diagnostic test threshold that leads to the highest sum of test sensitivity and specificity; determined by the point with the shortest distance to the top left-hand corner (0, 1) of the ROC curve.
Oral Glucose Tolerance Test (OGTT)	The gold standard test recommended for the diagnosis of prediabetes and diabetes by the World Health Organization. It involves fasting venous blood testing to determine Fasting Plasma Glucose (FPG) and 2-hour plasma glucose (2-hr PG) blood testing done 2 hours after a 75-gm glucose drink.

Positive Predictive Value (PPV)	The probability that participants with a positive test result have disease.
Prediabetes	Either Impaired Fasting Glucose (IFG), Impaired Glucose Tolerance (IGT), or both, using OGTT as follows: • IFG: FBS 6.1 – 6.9 mmol/l • IGT: 2-hr PG 7.8 – 11.0 mmol/l
Receiver operating characteristics (ROC) curve	A a graphical plot that illustrates the diagnostic ability of a binary classifier system as its discrimination threshold is varied, created by plotting the true positive rate on the y-axis against the false positive rate on the x-axis at various threshold settings. Used to calculate discrimination (area under the ROC curve), and determine optimal cut-off scores (thresholds).
Rural area	An area not classified as urban (Kenya National Bureau of Statistics, 2019).
Sensitivity	The ability of a test to detect disease when it is present.
Specificity	The ability of a test to exclude disease in participants without disease.
Urban area	A municipality or a town (Urban Areas and Cities Act, 2011; Kenya National Bureau of Statistics, 2019).
Waist Circumference (WC)	A measure of **abdominal obesity** measured using a measuring tape as the distance around a participant's body at the level of the umbilicus in centimetres (cm). Participants were categorized by three categories of WC: • Normal: WC < 94 cm (men); WC < 80 cm (women) • Moderate: WC 94 – 102 cm (men); WC 80 – 88 cm (women) • High: WC ≥ 102 cm (men); WC ≥ 88 cm (women)

CHAPTER 1: INTRODUCTION

1.1 General Background

Diabetes Mellitus (diabetes) is a chronic metabolic disorder that is characterized by hyperglycaemia due to defects in insulin secretion, action, or both (ADA, 2022). Type 2 diabetes, the most common type in adults, is characterized by insulin resistance and impairment in insulin secretion, which leads to chronic hyperglycaemia (ADA, 2022).

Prediabetes refers to a condition in which individuals have hyperglycaemia that is not high enough to meet the criteria for diagnosis of type 2 diabetes (ADA, 2022; Gavin et al., 1997; Genuth et al., 2003). It is recognized as a precursor to type 2 diabetes because it is associated with a higher risk of progression to type 2 diabetes as compared to normoglycemia (Gerstein et al., 2007; Perry & Baron, 1999; Tabák et al., 2012).

Diabetes is a major cause of morbidity and mortality worldwide, affecting about 537 million people aged between 20-79 years worldwide in 2021, with most of these affected people (80.6%) living in low- and middle-income countries (LMIC) like Kenya (IDF, 2021). This number is likely to increase to 783 million by 2045, with 94% of the increase expected to take place in LMIC. In Africa, more than half (53.6%) of affected adults aged 20-79 years are undiagnosed. The age standardized national prevalence of diabetes and prediabetes in Kenya was estimated to be 2.4% and 3.1% respectively in 2015, being higher in urban areas for both conditions; only 43.7% of participants that were diagnosed with raised fasting blood glucose or that were currently on medication for diabetes were aware of their glycaemic condition (MOH et al., 2015; Mohamed et al., 2018). More recent studies suggest differing prevalence of diabetes (as high as 16%) across different rural and urban communities (Ayah et al., 2013; El-Busaidy et al., 2014;

Githinji et al., 2017; Mathenge et al., 2010; Sarah et al., 2021); although these differing statistics may be due to differences in methodology, including inclusion criteria and diagnostic criteria for dysglycaemia, this may be an indicator of rising prevalence of dysglycaemia among rural communities of Kenya.

Early identification of type 2 diabetes while β-cell reserve is still high and complications have not set in, is cost-effective (Brandle et al., 2003; J. B. Brown et al., 1999); at this point, adequate glycaemic control can be achieved with lifestyle modifications and less expensive oral glucose-lowering agents like Metformin. Lifestyle interventions, and to a lesser extent, Metformin, reduce the risk of progression to type 2 diabetes among patients with prediabetes, hence the importance of identifying prediabetes (DPP Group, 2002; Gillies et al., 2007; Lindstrom & Tuomilehto, 2003; Pan et al., 1997; Perreault et al., 2012; Schellenberg et al., 2013; Tuomilehto et al., 2001). It is also possible to induce regression from prediabetes to normal glucose tolerance through intensive lifestyle modification (Perreault et al., 2009). It is therefore important to identify individuals with prediabetes and inform them about their increased risk for diabetes and cardiovascular disease, and counsel them about strategies to lower their risks.

Type 2 diabetes and its precursor, prediabetes, meet the requirements for disease conditions that are suitable for screening, including its morbidity and mortality burden, importance of early identification, and availability of suitable resources to diagnose and treat these ailments (WHO et al., 1968). However, due to the paucity of data on effectiveness of mass screening using blood glucose testing, non-invasive risk assessment tools have been developed as pre-screening tools in an effort to limit blood glucose testing to individuals with high likelihood of having dysglycaemia; this is

intended to improve cost-effectiveness and acceptability of diabetes screening (Buijsse et al., 2011; Noble et al., 2011). These tools are derived from known risk factors of type 2 diabetes (Robertson, 2019), and many of them have been shown to perform well, with good discriminative performance, especially among populations from which they were derived (Buijsse et al., 2011). They are consequently recommended for use by various expert groups (ADA, 2022; NICE, 2012; WHO & IDF, 2006).

One such tool is the **Finnish Diabetes Risk Score (FINDRISC)** (Lindstrom & Tuomilehto, 2003), an easy-to-use, valid, and freely available non-invasive pre-screening tool that is recommended for use by the International Diabetes Federation (IDF) (IDF, 2012). It is a one-page questionnaire containing eight questions of non-invasively measured risk factors for dysglycaemia: age, body mass index (BMI), waist circumference, hypertension, physical activity, diet, family history of diabetes, and history of glucose intolerance. It was derived from a ten-year prospective study for identification of individuals with a high risk for developing diabetes among the Finnish population (Lindstrom & Tuomilehto, 2003). Despite being developed for assessing risk for incident diabetes, it has good discriminatory performance in predicting prevalent as well as incident diabetes (Abbasi et al., 2012), and is among the most validated diabetes risk scores to date (N. Brown et al., 2012; Mbanya et al., 2015; Noble et al., 2011). It is also the only non-invasive risk assessment tool that has been extensively evaluated for use in sub-Saharan Africa, with moderately good results (Ephraim et al., 2020; Malindisa et al., 2021; Metonnou-Adanhoume et al., 2019; Omech et al., 2016; Traoré et al., 2021). Based on retrospective analysis of data on the Kenyan population, there are indications that FINDRISC has good discriminatory ability for detection of dysglycaemia among the Kenyan population (Mugume et al.,

2021). However, it remains unvalidated in a pragmatic setting, and there is therefore a need for further research on its utility in this setting.

1.2 Problem Statement

The current Kenya national screening programmes for dysglycaemia rely on mass screening using Random Blood Glucose (RBS) test and referral to health facilities for confirmatory Fasting Plasma Glucose (FPG) testing (MOH, 2018a). However, the high rate of undiagnosed diabetes in Kenya (>40%) (Mohamed et al., 2018) is one indicator of the suboptimality of the current screening strategy. This reflects the situation in the rest of Africa, which harbours the largest proportion of people with undiagnosed diabetes worldwide (IDF, 2021).

The World Health Organization (WHO), International Diabetes Federation (IDF) and American Diabetes Association (ADA) encourage selective multistage screening in resource-constrained settings (ADA, 2022; IDF, 2012; WHO, 2003). Using this strategy, high risk individuals are identified using a pre-selection criterion, and then subjected to a diagnostic test like the Oral Glucose Tolerance test (OGTT). The pre-selection criterion should preferably involve a population-specific diabetes risk score, which provides a cheaper and convenient alternative to mass screening using laboratory based diagnostic tests. This two-stage screening strategy, a non-invasive risk stratifying tool followed by a blood test, has been demonstrated to be the most cost-effective method of screening for diabetes and impaired glucose tolerance (Khunti et al., 2012).

However, most available diabetes risk scores were derived in and tested within non-African populations (N. Brown et al., 2012; Mbanya et al., 2015; Noble et al., 2011) and may not have the same discriminatory accuracy for African populations due to differences in population-specific characteristics. This includes the FINDRISC

questionnaire (Lindstrom & Tuomilehto, 2003), an easy-to-use, valid and freely available tool that is specifically recommended as a screening tool by the IDF (IDF, 2012).

1.3 Justification

Kenya, like many other sub-Saharan Africa countries, is faced with a large burden of undiagnosed dysglycaemia, resulting in late diagnosis and increased morbidity and mortality from complications. Current diabetes screening guidelines are not clear on how to identify high risk individuals who would benefit most from screening, despite mass screening being known not to be cost effective (IDF, 2012; WHO, 2003). There is therefore a need for a validated, effective, and simple questionnaire that would guide community-based screening in this region.

The FINDRISC questionnaire has been evaluated as a pre-screening tool for dysglycaemia in other sub-Saharan settings and shown to be useful, simple, and effective (Ephraim et al., 2020; Malindisa et al., 2021; Metonnou-Adanhoume et al., 2019; Omech et al., 2016; Traoré et al., 2021). There are indications that FINDRISC has good discriminatory ability for detection of dysglycaemia among the Kenyan population, based on analysis of the performance of a modified and simplified FINDRISC questionnaire on cross-sectional survey data from the Kenya STEPwise survey of 2015 (Mugume et al., 2021). However, its utility in a Kenyan pragmatic setting remains uncertain, hence the need to determine its discriminatory function in this setting.

1.4 Significance

This study sought to evaluate the utility of the FINDRISC questionnaire as a pre-screening tool for dysglycaemia in a Kenyan population. This was intended to inform its use as part of a potentially more cost-effective dysglycaemia screening practice in Kenya; this two-stage screening strategy, a non-invasive risk stratifying tool followed by a blood test, has been demonstrated to be the most cost-effective method for screening for diabetes and impaired glucose tolerance (Khunti et al., 2012).

1.5 Research Question

What is the diagnostic performance and optimal cut-off scores of the Finnish Diabetes Risk Score (FINSRISC) for detecting adults with undiagnosed dysglycaemia in a rural population of Western Kenya?

1.6 Objectives

Broad Objective

To evaluate the diagnostic performance of FINSRISC and determine its optimal cut-off scores for detecting adults with undiagnosed dysglycaemia in a rural population of Western Kenya.

Specific Objectives

- To evaluate the diagnostic performance (accuracy and discriminatory ability) of FINDRISC in detecting individuals with undiagnosed dysglycaemia.
- To determine the optimal FINDRISC cut-off scores for detecting undiagnosed dysglycaemia.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview of Prediabetes and Diabetes

2.1.1 Definition

Diabetes Mellitus (diabetes) is a chronic metabolic disorder that is characterized by high blood glucose (hyperglycaemia) due to defects in insulin secretion, action, or both (ADA, 2022). Type 2 diabetes is the most common type in adults (90 – 95%); it is characterized by chronic hyperglycaemia, insulin resistance, and impairment in insulin secretion (ADA, 2022).

Prediabetes is a condition in which blood glucose levels are high, but are not high enough to meet the criteria for type 2 diabetes (ADA, 2022; Gavin et al., 1997; Genuth et al., 2003). It includes individuals with impaired glucose tolerance (an abnormally high blood glucose after a meal) and/or impaired fasting glucose (an abnormally high blood glucose during fasting). It is recognized as a precursor to type 2 diabetes (Gerstein et al., 2007).

2.1.2 Epidemiology

Diabetes is a major cause of morbidity and mortality worldwide. About 537 million people aged between 20-79 years were living with diabetes in 2021 worldwide, and this number is estimated to increase to 783 million by 2045; 94% of this increase is expected to take place in low and middle-income countries (LMIC) like Kenya (IDF, 2021). About 80.6% of individuals aged between 20-79 years with diabetes live in LMIC, and more than half (53.6%) of these individuals are unaware of their disease status (IDF, 2021).

The age standardized national prevalence of diabetes and prediabetes in Kenya was estimated to be 2.4% (95% CI 1.8 - 3.0) and 3.1% (95% CI 2.2 - 4.0) respectively in 2015, with only 43.7% of participants diagnosed with raised fasting blood glucose or currently on medication for diabetes aware of their glycaemic condition (MOH et al., 2015; Mohamed et al., 2018). The prevalence was estimated to be higher in urban areas for both prediabetes (3.5% [95% CI: 1.6 - 5.3], versus 2.7%, [95% CI: 1.8 - 3.7]) and diabetes (3.4% [95% CI: 2.1 - 4.7], versus 1.9% [95% CI: 1.3 - 2.5]) (Mohamed et al., 2018). Other studies done in Kenya have suggested differing prevalence of dysglycaemia across different rural and urban communities (Ayah et al., 2013; El-Busaidy et al., 2014; Githinji et al., 2017; Mathenge et al., 2010; Sarah et al., 2021), with estimated prevalence of diabetes as high as 15.4% and 16% in rural populations of Meru and Isiolo respectively (El-Busaidy et al., 2014; Sarah et al., 2021). Although these differing statistics may be due to differences in methodology, including inclusion criteria and diagnostic criteria for dysglycaemia, this may be an indicator of rising prevalence of dysglycaemia among rural communities of Kenya.

Factors associated with diabetes in Kenya include older age, hypertension, and obesity, (Chege, 2010; D. L. Christensen et al., 2009; El-Busaidy et al., 2014; Githinji et al., 2017; MOH et al., 2015; Mohamed et al., 2018). Only education level was shown to be positively associated with pre-diabetes in Kenya; individuals with both incomplete primary and complete primary education had lower odds of having pre-diabetes compared to individuals having no formal education (MOH et al., 2015; Mohamed et al., 2018). Other factors that were investigated, but did not increase the odds for dysglycaemia, included gender and employment status (MOH et al., 2015; Mohamed et al., 2018).

Prediabetes is recognized as a precursor to type 2 diabetes. Those with impaired glucose tolerance (IGT) have a fivefold risk of type 2 diabetes, while those with impaired fasting glucose (IFG) have a sevenfold risk; individuals with both IGT and IFG have more than 12 times the risk of developing type 2 diabetes compared to normoglycemic individuals (Gerstein et al., 2007). They are also at high risk for cardiovascular disease (Perry & Baron, 1999).

Prediabetes, like type 2 diabetes, is associated with visceral (central) obesity, dyslipidaemia, and hypertension. Structured lifestyle interventions, aimed at increasing physical activity and producing weight loss, and the pharmacological agent Metformin, have been shown to prevent or delay the development of type 2 diabetes in people with prediabetes (DPP Group, 2002; Gillies et al., 2007; Lindstrom & Tuomilehto, 2003; Pan et al., 1997; Tuomilehto et al., 2001). It is also possible to induce regression from prediabetes to normal glucose tolerance through intensive lifestyle modification (Perreault et al., 2009). It is therefore important to identify individuals with prediabetes and inform them about their increased risk for diabetes and cardiovascular disease, and counsel them about strategies to lower their risks.

Diabetes and Age

The prevalence of diabetes increased with increasing age worldwide, from 2.2% among adults aged 20–24 years to 24.0% among adults aged 75–79 years (IDF, 2021). Similarly, the odds for having diabetes in Kenya increased with older age, being highest in 45–59 year old participants compared with 18–29 year olds (AOR 6.59) (MOH et al., 2015; Mohamed et al., 2018).

Diabetes and Hypertension

Hypertension is defined as either systolic blood pressure (SBP) ≥140 mmHg or diastolic blood pressure (DBP) ≥90 mmHg, or both (MOH, 2018b; Williams et al., 2018). Its prevalence in Kenya was estimated at 23.8% (95% CI 21.4 - 26.2) nationally during the STEPwise survey of 2015; the prevalence was higher among rural dwellers (25.3% [95% CI: 22.6 – 28]) than among urban dwellers (21.5% [95% CI: 17.4 - 25.5]), although the difference was not statistically significant (MOH et al., 2015).

Hypertension and type 2 diabetes are common comorbidities, hypertension being twice as frequent in patients with diabetes compared with those who do not have diabetes worldwide (Petrie et al., 2018). In Kenya, individuals with hypertension were 2.8 times more likely to have diabetes compared with normotensive individuals (MOH et al., 2015; Mohamed et al., 2018).

These conditions are closely interlinked because of similar risk factors, such as endothelial dysfunction, vascular inflammation, arterial remodelling, atherosclerosis, dyslipidaemia, and obesity; some aspects of their pathophysiology are also shared by these two conditions, particularly those related to obesity and insulin resistance (Mitchell et al., 1990; Petrie et al., 2018).

Diabetes and Overweight/Obesity

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health (WHO, n.d.). Type 2 diabetes and obesity are closely related, as described in the pathogenesis of diabetes below; they are connected by the tendency of obesity to induce both insulin resistance and deficiency. Obesity can be determined using several methods, including body mass index (BMI), waist circumference (WC),

waist to height ratio (WHtR), waist to hip ratio, conicity index, ponderal index, and percent ideal weight (Seo et al., 2017). However, BMI and WC are the most commonly used indicators because they are considered quick, inexpensive, yet effective predictors of disease outcomes (Seo et al., 2017).

Body mass index is calculated by dividing a person's weight in kilograms by his or her height in metres squared (kg/m^2). A BMI > 25 kg/m^2 is considered overweight, and > 30 kg/m^2 is considered obese (MOH, 2018a).

Waist circumference is the distance measured using a measuring tape around a participant's body at the level of the umbilicus in centimetres (cm) (MOH, 2018a). It is a measure of central obesity, an indicator of high visceral adipose tissue and high subcutaneous adipose tissue in the abdominal area (Seo et al., 2017). Men with WC ≥ 102 cm and women with WC ≥ 88 cm are at an increased risk of diabetes (NHLBI, 1998).

The Kenya STEPwise survey estimated a 27.9% prevalence of overweight and obese in 2015, being significantly higher in women (38.5% [95% CI 34.4 - 42.7]) than men (17.5% [95% CI 13.2 - 21.8]) (MOH et al., 2015). The rural prevalence of overweight and obese (15.5% [95% CI 13.3 - 17.7] and 6.9% [95% CI 5.2 - 8.6] respectively) was significantly lower than urban prevalence (24.6% [95% CI 20.2 - 28.9] and 12.2% [95% CI 9.8 - 14.6] respectively). The mean waist circumference for men and women was 78.6cm (95% CI 76.7 - 80.4) and 79.1cm (95% CI 77.4 - 80.7) respectively.

In a meta-analysis done to compare BMI and WC, WC ≥ 102cm (in men) and ≥ 88 cm (in women) seemed to be better at predicting development of diabetes than BMI ≥ 30 (Seo et al., 2017). WC was also a stronger predictor for diabetes development for women compared to men, and in individuals aged 60 and older.

2.1.3 Pathogenesis

Type 2 diabetes develops from the concurrence of insulin resistance (decreased ability of insulin to act effectively on target tissues) and abnormal insulin secretion; the insulin resistance precedes the insulin secretory defect, and diabetes develops when pancreatic insulin secretion is unable to overcome the insulin resistance (Powers et al., 2018).

Genetics has a role in the pathogenesis of type 2 diabetes, evidenced by the high concordance in identical twins of between 70 - 90% (Powers et al., 2018). Individuals with a parent with type 2 diabetes also have an increased risk of diabetes; the risk approaches 40% if both parents have type 2 diabetes. Insulin resistance is also present in many non-diabetic, first-degree relatives of individuals with type 2 diabetes.

However, despite the strong genetic component, environmental factors are required to produce disease. The major environmental risk factors include obesity, poor nutrition, and physical inactivity/sedentary lifestyle; other risk factors include either increased or reduced birth weight, and children of pregnancies complicated by gestational hyperglycaemia (Powers et al., 2018).

Pathophysiology of type 2 diabetes

Type 2 diabetes is characterized by insulin resistance, impaired insulin secretion, excessive hepatic glucose production, abnormal fat metabolism, and systemic low-grade inflammation (Powers et al., 2018).

The natural history of type 2 diabetes is illustrated in Figure 1 below. In the early stages of disease (A to B), increase in peripheral insulin resistance is matched by a compensatory increase in insulin production by the pancreatic beta cells (compensatory hyperinsulinemia) (Kahn, 2001). Glucose tolerance therefore remains normal (normal

glucose tolerance [NGT]). However, the pancreatic islets in at-risk individuals are unable to sustain this hyper-insulinemic state; this results in impaired glucose tolerance (IGT), characterized by elevations in postprandial glucose (stage C). A further decline in insulin secretion and an increase in hepatic glucose production leads to fasting hyperglycaemia (impaired fasting glucose [IFG]). Beta cell failure eventually ensues, leading to overt type 2 diabetes (stage D) characterized by chronic hyperglycaemia.

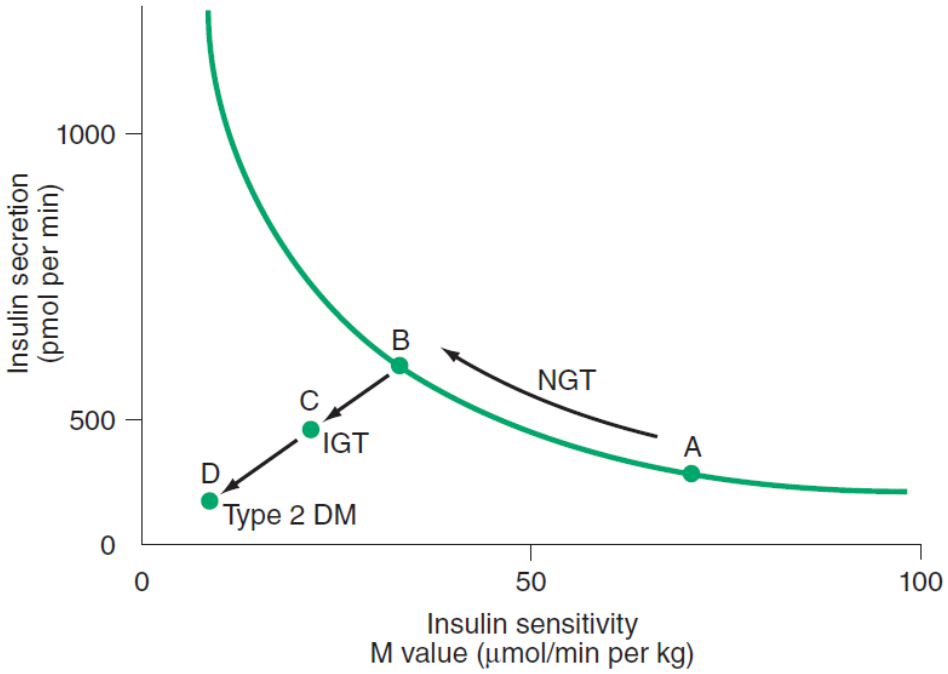


Figure 1: Natural History of Type 2 Diabetes. Adapted from (Kahn, 2001; Powers et al., 2018)

The natural history from NGT to IGT/IFG to overt diabetes highlights the importance of recognizing individuals with IGT and IFG since such individuals are at an increased risk of type 2 diabetes (Gerstein et al., 2007). IGT and IFG are therefore collectively referred to as **prediabetes**.

Insulin resistance is the hallmark of type 2 diabetes (Powers et al., 2018); it may be driven by obesity, especially visceral (central) obesity that is common in type 2 diabetes (≥80% of patients are obese) (Powers et al., 2018). The high adipocyte (fat cell) mass

present in obesity leads to increased levels of circulating *free fatty acids* and *cytokines (adipokines)* in the blood.

Free fatty acids have various effects (Powers et al., 2018). Firstly, they increase skeletal muscle insulin resistance by promoting impaired glucose utilization in the muscle. Secondly, they increase hepatic insulin resistance, leading to increased glucose production by the liver. Thirdly, they impair pancreatic beta cell function, leading to reduced insulin secretion.

Adipokines, like free fatty acids, also cause increased insulin resistance in the skeletal muscle and liver. Conversely, the production of *adiponectin* (an insulin-sensitizing peptide) by adipocytes is reduced in obesity; this contributes to further hepatic insulin resistance (Powers et al., 2018).

The ensuing insulin resistance leads to *fasting hyperglycaemia* and *postprandial hyperglycaemia* due to increased hepatic glucose production and decreased peripheral glucose utilization, respectively (Powers et al., 2018).

Insulin secretion initially increases in response to insulin resistance to maintain NGT. Thereafter, there is a decline in the insulin secretory capacity of pancreatic beta cells in type 2 diabetes that is progressive, with worsening hyperglycaemia over time. This is caused by decreased pancreatic beta cell mass, and the unfavourable metabolic environment of diabetes. This is because chronic hyperglycaemia paradoxically impairs insulin secretion by impairing pancreatic islet function (“glucose toxicity”); while the high levels of free fatty acids (“lipotoxicity”), and adipokines increase insulin resistance (Powers et al., 2018).

Excessive hepatic glucose results from hepatic resistance to insulin, leading to gluconeogenesis even in the presence of hyperinsulinemia. This causes fasting hyperglycaemia and decreased glycogen storage by the liver in the postprandial state (Powers et al., 2018).

Abnormal fat metabolism is mediated by the insulin resistance present in adipose tissue. This insulin resistance leads to lipolysis with resultant increased free fatty acid flux from adipocytes. These free fatty acids are transported to the liver by blood, leading to increased hepatocyte synthesis and secretion of very-low-density lipoprotein [VLDL]-triglyceride). This is responsible for the dyslipidaemia found in type 2 diabetes, characterised by elevated triglycerides, reduced high-density lipoprotein (HDL) and increased small dense low-density lipoprotein (LDL) particles. This dyslipidaemia is associated with steatosis in the liver, which may lead to non-alcoholic fatty liver disease (NAFLD) and abnormal liver function tests (Powers et al., 2018).

Systemic low-grade inflammation is mediated by adipokines and other adipocyte products that produce an inflammatory state, leading to elevations in markers of inflammation such as IL-6 and C-reactive protein (CRP) (Powers et al., 2018).

2.1.4 Clinical features

Type 2 diabetes is generally asymptomatic unless the patient presents with complications of diabetes or with marked hyperglycaemia (Imam, 2013). It is therefore frequently diagnosed incidentally by discovery of hyperglycaemia during routine clinical visits. Symptoms of marked hyperglycaemia include polyuria, polydipsia, weight loss, sometimes with polyphagia, and blurred vision (Imam, 2013).

Complications of diabetes may be acute (including diabetic ketoacidosis and hyperosmolar hyperglycaemic state), or chronic (including diabetic retinopathy, nephropathy, and neuropathy; or cardiovascular disease like heart disease or stroke) (Imam, 2013).

2.2 Screening for Prediabetes and Type 2 Diabetes

2.2.1 Rationale for Screening

The following principles determine disease conditions that are suitable for screening (WHO et al., 1968):

- The condition sought should be an important health problem.
- There should be an accepted treatment for patients with recognized disease.
- Facilities for diagnosis and treatment should be available.
- There should be a recognizable latent or early asymptomatic stage.
- There should be a suitable test or examination.
- The test should be acceptable to the population.
- The natural history of the condition, including development from latent to declared disease, should be adequately understood.
- There should be an agreed policy on whom to treat as patients.
- The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care.
- Case-finding should be a continuing process and not a "once and for all" project.

Type 2 diabetes and its precursor, prediabetes, appear to meet the above requirements. Firstly, type 2 diabetes is a major cause of morbidity and mortality worldwide, and its prevalence is rising (IDF, 2021).

Secondly, treatment strategies for type 2 diabetes and their benefits are well established in literature; many expert groups have published guidelines on the management of type 2 diabetes, highlighting treatments that are acceptable to patients and that have shown a morbidity and/or mortality benefit among patients (ADA, 2022; IDF, 2012; MOH, 2018a). Early recognition and treatment of type 2 diabetes is also important in prevention of occurrence and progression of its complications (DCCT Group, 1993; UKPDS Group, 1998).

Type 2 diabetes has a long asymptomatic period (Pirart, 1978), and diagnosis is usually made when complications have already set in. Its natural history is also well described and includes a prediabetic phase (IGT and/or IFG) whereby individuals are at risk of macrovascular complications and progression to type 2 diabetes with its associated microvascular and macrovascular complications (Powers et al., 2018).

There exist suitable screening blood tests for type 2 diabetes, including glycated haemoglobin (HbA1C), Fasting Plasma Glucose (FPG) and the two-hour Oral Glucose Tolerance Test (OGTT) (ADA, 2022; MOH, 2018a; WHO & IDF, 2006). In addition to these tests, non-invasive risk assessment tools (questionnaires) have been developed as pre-screening tools in an effort to limit invasive blood testing; this is intended to improve cost-effectiveness and acceptability of diabetes screening (Buijsse et al., 2011; Noble et al., 2011).

Expert groups, including the World Health Organization, International Diabetes Federation and the American Diabetes Association, have developed guidelines on the

diagnosis and management of type 2 diabetes, providing evidence-based cut off points for NGT, IGT, IFG and type 2 diabetes (ADA, 2022; IDF, 2012; WHO & IDF, 2006).

Early identification of type 2 diabetes before complications have progressed, and while β-cell reserve is still is high, is more cost-effective (Brandle et al., 2003; J. B. Brown et al., 1999); at this point, adequate glycaemic control can be achieved with lifestyle modifications and less expensive oral glucose-lowering agents like Metformin. Lifestyle interventions and Metformin reduce the risk of progression to type 2 diabetes among patients with IGT (Perreault et al., 2012; Schellenberg et al., 2013), highlighting the importance of identifying prediabetes.

Lastly, expert groups recommend continuous screening for type 2 diabetes, more so among individuals at high risk of the same (ADA, 2022; WHO & IDF, 2006).

2.2.2 Screening Tests for Prediabetes and Type 2 Diabetes

All tests that are used to diagnose prediabetes or diabetes can be used for screening. They include the Oral Glucose Tolerance Test (OGTT), fasting plasma glucose (FPG) and glycated haemoglobin (HbA1C). Table 1 below summarizes the WHO diagnostic criteria for prediabetes and diabetes (WHO, 2011; WHO & IDF, 2006).

Table 1: WHO criteria for the Diagnosis of Diabetes Mellitus and Intermediate Hyperglycaemia

Diabetes	
Fasting plasma glucose	≥7.0 mmol/l
2–h plasma glucose	≥11.1 mmol/l
HbA1C	≥6.5%
Impaired Glucose tolerance (IGT)	
Fasting plasma glucose	<7.0 mmol/l **and**
2–h plasma glucose	7.8 to 11.0 mmol/l
Impaired Fasting Glucose (IFG)	
Fasting plasma glucose	6.1 to 6.9 mmol/l **and**
2–h plasma glucose	<7.8 mmol/l

Oral Glucose Tolerance Test (OGTT)

The OGTT is regarded by the WHO as the gold standard test for the diagnosis of both prediabetes and diabetes (WHO & IDF, 2006). Its procedural aspects are described in Appendix D: Oral Glucose Tolerance Test (OGTT) Procedure.

It is the most sensitive test for prediabetes because it is the only test that can reliably detect IGT. It is also more sensitive than FPG and HbA1C in the diagnosis of diabetes (Gavin et al., 1997).

However, it has some disadvantages. It is prone to variation, which may affect reproducibility of results; this is due to its reliance on glucose levels that are susceptible to variation within an individual (Gavin et al., 1997; Genuth et al., 2003). It also requires an overnight fast of at least 8 hours, making it inconvenient (WHO, 1985).

Fasting Plasma Glucose (FPG)

FPG is recommended by the ADA due to its perceived better practicality (ADA, 2022). However, like OGTT, it has the disadvantage of requiring a fasting state.

It is also less sensitive than OGTT in diagnosing both prediabetes and diabetes. A meta-analysis done to assess the diagnostic accuracy of tests for detecting type 2 diabetes from community settings demonstrated a summary sensitivity and specificity of 59.4% (95% CI: 46.6 - 71%) and 98.8% (95% CI: 96.5 - 99.6%) respectively of FPG for the detection of type 2 diabetes, using OGTT as the reference standard (Kaur et al., 2020). This meta-analysis included a study done in South Africa that demonstrated a sensitivity and specificity of 40% (95% CI: 32 – 48%) and 99% (95% CI: 98 – 99%) respectively (Prakaschandra & Prakesh Naidoo, 2018).

Another study done in a rural South African community demonstrated that if FPG results alone were used, the prevalence of diabetes would be 36% lower and that none of the subjects with IGT would be identified (Motala et al., 2008). Use of FPG alone was also found to be ineffective in ruling out glucose intolerance (Sainaghi et al., 2007).

Haemoglobin A1C (HbA1C)

This is molecule formed when glucose binds to haemoglobin A in the blood. It is a marker of chronic glycaemia, reflecting average blood glucose levels over a 2- to 3-months' period. Apart from its role in the follow up of patients on management for diabetes, it has been recommended as a screening and diagnostic tool for prediabetes and diabetes due to its advantages, which include greater patient convenience (since no special preparation or timing is required), and less day-to-day intra-individual variability (since it reflects the average exposure to glucose and is therefore less affected by acute glucose fluctuations that occur during periods of stress and illness) (Nathan et al., 2009; WHO, 2011).

However, it is not routinely available in many sub-Saharan African countries, likely due to its higher cost and stringent controls recommended by the National Glycohemoglobin Standardization Program (NGSP) (WHO, 2011).

It has also been majorly validated for use among Caucasian populations. There is some evidence that ethnic factors may affect its diagnostic accuracy and utility, which suggests that the WHO recommended diagnostic cut-off points of ≥ 5.6% and 6.5% for prediabetes and diabetes respectively (WHO & IDF, 2006) may not be optimal in other (non-Caucasian) populations. For instance, a cut-off of ≥ 6.1% was shown to have better diagnostic performance than a cut-off of ≥ 6.5% in an Indian population (Mohan et al., 2010), while the optimal HbA1C cut-off for detection of diabetes in a South African

population was 6.0% when OGTT was used as the gold standard test (Hird et al., 2016). In the South African study, an HbA1C of 6.5% had a sensitivity and specificity of 70.3% (95% CI: 52.7 – 87.8%) and 98.7% (95% CI: 97.9 – 99.4) respectively for the detection of diabetes, while the same cut-off had a sensitivity of 78.2% in the Indian study. This seems to be the case with prediabetes too; the diagnostic sensitivity and specificity of A1C for the detection of prediabetes was 50% (95% CI: 39 – 61%) and 75% (95% CI 67 – 81%%) among Africans living in America (Sumner et al., 2016). Other studies report sensitivities ranging from 31.6 to 86.2%, and specificities ranging from 56.3 to 93.3% of HbA1C for the detection of prediabetes (Bhowmik et al., 2013; Guo et al., 2014; Kharroubi et al., 2014; Zhou et al., 2009).

A meta-analysis done to assess the diagnostic accuracy of tests for detecting type 2 diabetes from community settings that included the study by Hird et al. above (Hird et al., 2016) demonstrated a summary sensitivity and specificity of 50% (95% CI: 42 – 59%) and 97% (95% CI: 95–98%) respectively at a common cut-off of 6.5% for detecting diabetes using OGTT as the reference standard (Kaur et al., 2020).

Furthermore, since the assay is dependent on red blood cell survival and turnover, the following factors may interfere with A1C results (NGSP, 2019): haemoglobin variants e.g., HbS, HbC and elevated foetal haemoglobin [HbF] (Little & Roberts, 2009), iron deficiency anaemia (IDA) [a major public health problem in developing countries] (Coban et al., 2004; El-Agouza et al., 2002; Sinha et al., 2012), haemolytic anaemia (Horton & Huisman, 1965), chronic renal failure (Boer et al., 1980; Grimm et al., 1981; Paisey et al., 1986) and HIV infection (Diop et al., 2007; Eckhardt et al., 2012; Kim et al., 2009). All these factors are highly prevalent in sub-Saharan African countries, which limits the utility of HbA1C in this setting.

2.2.3 Risk Scores for Screening for Prediabetes and Type 2 Diabetes

Risk assessment tools have been developed as a strategy to guide screening for diabetes. They are derived from known risk factors of type 2 diabetes, which include (Robertson, 2019):

- **Prediabetes:** HbA1C ≥5.7%, impaired glucose tolerance (IGT) or impaired fasting glucose (IFG)
- Age ≥45 years
- Obesity (body mass index [BMI] ≥25 kg/m^2)
- Family history of diabetes mellitus
- Sedentary lifestyle or physical inactivity
- Certain ethnicities or racial groups e.g., African American, Hispanic, Native American, Asian American, and Pacific Islanders
- Dietary patterns e.g., consumption of red meat, processed meat, and sugar
- Hypertension (blood pressure ≥140/90 mmHg)
- Dyslipidaemia: serum high-density lipoprotein cholesterol concentration ≤0.9 mmol/L and/or serum triglyceride concentration ≥2.8 mmol/L
- Certain medical conditions: History of gestational diabetes mellitus, Polycystic ovary syndrome and the metabolic syndrome
- History of vascular disease

Expert groups recommend selective screening for prediabetes and diabetes among individuals with the above risk factors (high-risk groups), rather than population based (non-selective) screening (ADA, 2022; WHO & IDF, 2006).

Risk assessment tools simplify these risk factors into scoring systems, including simple questionnaires, which are easier to employ. A score is assigned for each risk factor, and the total score is used to assign a certain degree of risk to an individual. This score is then used to pre-select individuals for diagnostic laboratory screening. Since the different risk factors for diabetes confer some risk of future diabetes, it follows then that a well-designed risk assessment tool would accurately predict individuals at risk for diabetes. A number of tools have subsequently been shown to perform well in this regard, with good discriminative performance, especially among populations from which they were derived (Buijsse et al., 2011). Some of these tools have also proven useful in predicting prevalent diabetes in addition to future risk of diabetes, further proving their utility in identifying individuals that would benefit more from diagnostic testing (N. Brown et al., 2012).

Other than their potential utility in limiting screening to high-risk individuals, they also help optimise resources for screening. This is because definite diagnosis of prediabetes and diabetes requires invasive blood testing. Risk scores therefore identify high-risk individuals who would benefit more from this testing and limits testing of low-risk individuals. This is especially important in the resource strained sub-Saharan African countries. Self-administered risk questionnaires also have the potential to be used as health promotion tools, helping to inform individuals of risk factors for prediabetes and diabetes; this provides a channel to promote awareness about diabetes and open discussions about lifestyle changes among individuals with, or at risk for, prediabetes or diabetes.

However, most of these tools perform somewhat worse in populations other than those they were derived from (N. Brown et al., 2012; Buijsse et al., 2011; Glumer et al.,

2006). This is a potential limitation of their use in the low- and middle-income countries of sub-Saharan Africa which has the largest proportion of undiagnosed diabetes, since none of the existing tools were developed from this region (Mbanya et al., 2015). Furthermore, little research has been undertaken to determine the utility and performance of the tools in this population.

2.2.4 Finnish Diabetes Risk Score (FINDRISC)

The Finnish Diabetes Risk Score (FINDRISC) is one of the risk assessment tools that was developed to predict the risk of developing type 2 diabetes; it was derived from a 10-year prospective study for identification of people at high risk of developing type 2 diabetes among the Finnish population (Lindstrom & Tuomilehto, 2003). It was intended to be a simple risk calculator that could be conveniently used in primary care and by lay individuals themselves; it therefore comprises the following non-invasively measured parameters: age, body mass index (BMI), waist circumference, hypertension, physical activity, diet, family history of diabetes, and history of glucose intolerance. Each parameter is scored, with a maximum score of 26 (Appendix C.1: Original FINDRISC Questionnaire). The risk of developing T2DM within 10 years is classified as follows:

- Low (<7)
- Slightly elevated (7-11)
- Moderately elevated (12-14)
- High (15-20)
- Very high (>20)

The FINDRISC questionnaire demonstrated good discriminatory performance (accuracy and discriminatory ability) in predicting both incident and prevalent diabetes. It had a

very good discriminatory ability for the detection of incident diabetes, given an area under the receiver operating characteristics curve (AUROC) of 0.85 and 0.87 for the 1987 and 1992 cohorts respectively. The optimum cut-off core was ≥9 with an associated sensitivity and specificity of 78% and 77% respectively in the 1987 cohort, and sensitivity and specificity of 81% and 76% respectively in the 1992 cohort. The positive predictive value (PPV) of incident diabetes was 13% for 1987 cohort (10-year follow-up) and 5% for the 1992 cohort (5- year follow-up with subsequent lower incidence). The diagnostic performance for prevalent diabetes was similar to its performance for incident diabetes, demonstrating an AUROC of 0.80 among both cohorts. The optimum cut-off point for prevalent diabetes was also ≥9; at this cut-off point, the 1987 cohort demonstrated a sensitivity and specificity of 77% (95% CI: 66 - 85) and 66% (95% CI: 64 - 68) respectively, while the 1992 cohort demonstrated a sensitivity and specificity of 76% (95% CI: 67 - 83) and 68% (95% CI: 66 - 70) respectively.

Given its appealing attributes, it is among the most validated diabetes risk scores to date (N. Brown et al., 2012; Mbanya et al., 2015; Noble et al., 2011), and is recommended as a pre-screening tool by the IDF (IDF, 2012). It performed the best among the tools evaluated in an external validation study that incorporated only non-invasive measures (Abbasi et al., 2012), having an AUROC was 0.85, which matched its development validation performance of 0.86.

The FINDRISC questionnaire was also identified as among the seven most promising tools that should be prioritised by clinicians in their practice because of generalisability, statistically significant calibration, good discrimination (AUROC > 0.70) and usability (10 or fewer components) (Noble et al., 2011).

Furthermore, it is the only non-invasive risk assessment tool that has been validated in Africa. A study utilizing retrospective data of Kenyan adults aged 18-69 years extracted from the 2015 Kenya STEPwise cross-sectional survey (MOH et al., 2015) evaluated the performance of a modified and simplified FINDRISC questionnaire (Mugume et al., 2021). The FINDRISC score was modified based on data availed during the National survey; the primary study data collection instrument had no questions on parental/family history of diabetes but collected data on the other FINDRISC tool question components: age, BMI, waist circumference, physical activity, fruit and/or vegetable consumption, personal histories of hypertension and diabetes (MOH et al., 2015). Since the respective scores for the different risk factor components were maintained, the maximum score of the modified FINDRISC questionnaire reduced from 26 of the original FINDRISC questionnaire to 20. The modified FINDRISC was further simplified (to create the simplified FINDRISC questionnaire) by excluding the fruit and/or vegetable consumption and physical activity variables based on logistic regression and receiver operating characteristics (ROC) curve analyses that demonstrated that they did not significantly influence the area under the receiver operating characteristics (AUROC) in detecting undiagnosed diabetes; thus only age, BMI, waist circumference and histories of diabetes and hypertension were retained, creating a simplified FINDRISC questionnaire with a maximum score of 18. The modified FINDRISC questionnaire had good discriminatory ability in detecting undiagnosed type 2 diabetes and prediabetes, given an AUROC of 0.748 (95% CI: 0.692 – 0.804) and 0.631 (95% CI: 0.576 – 0.685) respectively; the simplified FINDRISC questionnaire had similar good discriminatory ability to the modified FINDRISC questionnaire with an AUROC of 0.749 (95% CI: 0.692–0.805) and 0.636 (95% CI: 0.583–0.688) for detection of undiagnosed type 2 diabetes and prediabetes

respectively (Mugume et al., 2021). However, the modified FINDRISC questionnaire had a 2% higher sensitivity (59.6% versus 57.6%) but a 3.3% lower specificity (83.0% versus 79.7%) than the simplified FINDRISC questionnaire at a cut-off score of ≥ 7; both questionnaires had a low positive predictive value (PPV) of 6.9 and 7.9% respectively but a high negative predictive value (NPV) of 98.7%. Despite these indications that FINDRISC may perform well in this sub-Saharan setting of Kenya, there is to date no published study that has assessed its diagnostic performance in a pragmatic study setting.

In a cross-sectional study done in Botswana involving patients aged ≥ 20 years attending outpatient clinics in 2014 (Omech et al., 2016), FINDRISC was found to have sufficient discriminatory ability in predicting undiagnosed diabetes (AUROC of 0.63, 95% CI: 0.55–0.72), with a sensitivity and specificity of 48% and 73% respectively at an optimal cut-off point of ≥17; the PPV was 20% while the NPV was 89.5%. A possible reason for this less impressive performance included the use of HbA1C as the gold standard test in this study which has a lower sensitivity in sub-Saharan African populations (Dirk L. Christensen et al., 2010; Zemlin et al., 2011). Use of HbA1C instead of OGTT was similarly shown to impair the discriminatory ability of FIDNRISC for detecting type 2 diabetes in a Spanish Mediterranean population (Costa et al., 2013).

Another cross-sectional study done among 259 participants aged 18–35 years in an urban setting of Mwanza in Tanzania demonstrated poor sensitivity and specificity of 39.1% (95% CI: 27.1 - 52.1) and 69.2% (95% CI: 62.2 - 75.6) respectively of FINDRISC for detection of dysglycaemia (both prediabetes and diabetes) at a cut-off point of ≥7, with a poor discriminatory ability in that population, given an AUROC of

0.54 (95% CI: 0.47 - 0.61); the PPV was 29.4% (95% CI 20.0 - 40.3), while the NPV was 77.6% (95% CI: 70.7 - 83.5) (Malindisa et al., 2021). prediabetes and diabetes were defined using WHO criteria, with OGTT as the gold standard test for diagnosis. Possible reasons given for this poor performance included: young age of participants (below 45 years of age), which made it difficult to discriminate a risk score based on the age category; need to adapt the questionnaire to a Tanzanian African setting since the types of fruits and vegetables consumed in that population differed compared to the Finnish population; and the fact that ascertaining family history of diabetes mellitus as required in the FINDRISC questionnaire may have been unrealistic since most cases of diabetes remain undiagnosed due to poor health-seeking habits. The authors recommended the development of a modified (adapted) tool to increase the usefulness of FINDRISC as a pre-screening tool.

In another cross-sectional study among 135 fishermen from three fishing communities (Duakor, Ola and Moree) in Cape Coast located in the Central Region of Ghana, FINDRISC demonstrated a sensitivity and specificity of 58.3% and 86.9% respectively for the detection of type 2 diabetes at an optimal cut-off score of ≥13.5, with good discriminatory ability, given an AUROC of 0.76 (95% CI: 0.68 – 0.83) (Ephraim et al., 2020). Type 2 diabetes was diagnosed using WHO fasting plasma glucose (FPG) criteria as the gold standard test for diagnosis.

In another cross-sectional study among 1276 participants aged 18 - 80 years from the city of Ouagadougou in Burkina Faso, FINDRISC demonstrated a sensitivity and specificity of 70.80% and 62.07% respectively for the detection of type 2 diabetes at an optimum cut-off score of ≥7, with good discriminatory ability, given an AUROC of 0.70 (95% CI: 0.65 – 0.74) (Traoré et al., 2021). Type 2 diabetes was diagnosed using

WHO criteria, with OGTT as the gold standard test for diagnosis; the estimated prevalence of type 2 diabetes in this population was 10.74%. During the conduct of this study, the original FINDRISC questionnaire was adopted to suit the local language. For instance, questions about intake of vegetables and fruits utilized locally available examples like spinach, lettuce, tomatoes, squash, green beans, orange, banana, and apple, while utilizing locally understandable methods of estimating portions like a bowl (or half a bowl) of vegetables, or medium-sized fruit, or a bowl (or half a bowl) of fruits.

In a study done among 1000 participants from Algiers in Algeria, FINDRISC demonstrated a sensitivity and specificity of 68% and 64% respectively for the detection of diabetes at an optimum cut-off score of ≥13 and ≥14 in women and men respectively, with sufficient discriminatory ability, given an AUROC of 0.64 (95% CI: 0.60 – 0.68) (Azzouz et al., 2014). It further demonstrated a sensitivity and specificity of 86% and 41% respectively for the detection of dysglycaemia (both prediabetes and diabetes) at the same optimum cut-off scores, with sufficient discriminatory ability, given an AUROC of 0.67 (95% CI: 0.64 – 0.70). Dysglycaemia was diagnosed using WHO criteria, with OGTT as the gold standard test for diagnosis.

Lastly, in one study that utilized retrospective data of 536 participants aged 25 to 65 years from southern Benin, extracted from a national survey, FINDRISC demonstrated a sensitivity and specificity of 77% and 89% respectively for the detection of type 2 diabetes at an optimal cut-off score of ≥8.5, with very good discriminatory ability, given an AUROC of 0.86 (95% CI: 0.81 – 0.90) (Metonnou-Adanhoume et al., 2019). Type 2 diabetes was diagnosed using WHO fasting plasma glucose (FPG) criteria as the gold standard test for diagnosis.

Outside Africa, FINDRISC demonstrated a sensitivity and specificity of 72.13% and 65.48% respectively for detecting undiagnosed diabetes at an optimal cut-off score of ≥11 among a multiracial study population of the United States of America with good discriminatory ability, given an AUROC of 0.75; it had a sensitivity and specificity of 59.34% and 65.43% respectively at an optimal cut-off score of ≥10 for detecting prediabetes, with sufficient discriminatory ability, given an AUROC of 0.67. In a Greek population living in Athens, it demonstrated a good discriminatory ability for both diabetes and any degree of dysglycaemia (both prediabetes and diabetes), given an AUROC of 0.724 (95% CI: 0.677 – 0.770) and 0.716 (95% CI: 0.68 – 0.752) respectively; it had a sensitivity and specificity of 81.1% and 59.8% respectively for detection of undiagnosed diabetes at an optimal cut-off off score of ≥15, and a sensitivity and specificity of 67.7% and 67.2% respectively for the detection of any dysglycaemia (both prediabetes and diabetes) at the same optimal cut-off score of ≥15 (Makrilakis et al., 2011). A large study of 2169 participants in Bulgaria demonstrated good discriminatory ability of FINDRISC for detection of both diabetes and dysglycaemia (both prediabetes and diabetes), given an AUROC of 0.708 (95% CI: 0.685–0.731) and 0.701 (95% CI: 0.672–0.731) respectively; it sensitivity and specificity for detection of undiagnosed diabetes was 78% (95% CI: 73 - 85) and 62% (95% CI: 58 – 68) respectively at the optimal cut-off score of ≥12, while the sensitivity and specificity was 84% (95% CI: 71 – 90) and 61% (54 – 71) respectively for the detection of dysglycaemia (both prediabetes and diabetes) at the optimal cut-off score of ≥10 (Tankova et al., 2011).

2.2.5 Screening for Type 2 Diabetes in Kenya

The National Diabetes Prevention and Control Program of Kenya recommends screening for dysglycaemia, since early diagnosis is crucial to reducing morbidity and mortality related to dysglycaemia (MOH, 2018a). It recommends that screening be considered for all individuals with any risk factors; high risk groups that should be prioritized for screening include: overweight or obese individuals, individuals with a first-degree relative with diabetes, women previously diagnosed with gestational diabetes mellitus (GDM) or who delivered a baby weighing > 4 kg, individuals with a history of cardiovascular disease, individuals with Hypertension, individuals with Dyslipidaemia, women with Polycystic Ovarian Syndrome, individuals who participate in <150 minutes of moderate activity per week, individuals with clinical conditions associated with insulin resistance (e.g. severe obesity, acanthosis nigricans), and individuals with unhealthy diets (MOH, 2018a).

The Kenyan National guidelines are however silent on how community-based screening should be approached. However, the guidelines recommend that diagnosis of diabetes in asymptomatic individuals be made by firstly screening using a random blood glucose (RBS) test; individuals with RBS ≥ 11 mmol/l should then be referred for diagnostic testing. If screening results are normal, repeat testing should be done with consideration of ongoing risk status (MOH, 2018a). Use of risk assessment tools that are recommended by the WHO, IDF and ADA do not feature in the guidelines, likely due to inadequate evidence for their use in this region.

CHAPTER 3: METHODOLOGY

3.1 Study Design

This study was conducted in two phases; the main study was preceded by a **pilot phase** to translate and pilot the study instrument and determine the participating study sites.

A **cross-sectional study design** was employed for the main study. This design allowed us to assess the diagnostic performance of FINDRISC across various socio-demographic groups (e.g., different age strata, sex, educational and employment status) in an efficient manner.

3.2 Study Site

This study was conducted in Wehoya, Toro and Kaptien villages of Sirende ward in Kiminini sub-county, Trans-Nzoia county. As shown in Figure B 1, Trans-Nzoia County is one the forty-seven counties in Kenya, situated in western Kenya; it borders the Republic of Uganda to the West, Bungoma and Kakamega Counties to the South, West Pokot County to the East, Elgeyo Marakwet and Uasin Gishu Counties to the Southeast (County Government of Trans-Nzoia, 2020). Kiminini sub-county, as shown in Figure B 2, is one of the five administrative units (sub-counties) of Trans-Nzoia County; others include Cherangany, Saboti, Kwanza, and Endebess.

Trans-Nzoia county was one of the regions served by the Primary Health Integrated Care Project for Chronic Conditions (PIC4C). This was a pilot project based in Busia and Trans Nzoia counties that aimed to identify people with hypertension, diabetes, cervical and/or breast cancer in the community and facilitate their referral and management at the appropriate service level, in addition to sensitizing them on and linking them to the National Hospital Insurance Fund (NHIF) (UK Research and

Innovation, n.d.). Individuals were mobilized by community health volunteers (CHVs) to appear for screening at pre-selected screening booths, where screening was done by community health promoters (CHPs) and screen-positive individuals appropriately referred to care at the nearest health facility. This study took advantage of this existing PIC4C platform; study participants were voluntarily recruited at the screening booth level within the participating sites described above and subsequently referred to the nearest testing site for diabetes screening and participation into the study.

The participating sites were selected on the basis of the closer proximity of Kiminini sub-county to the participating laboratory than the other sub-counties of Trans-Nzoia; availability of infrastructure to support the study, including road network and structures to set up phlebotomy areas (with electricity connection and biohazard waste management structures); study sites/booths that had not been exhausted by the ongoing screening; and existence of a network of CHVs for participant mobilization.

Kiminini sub-county also boasts a high level of literacy, with 92.5% and 90.9% of the male and female population respectively having attended at least basic education (Kenya National Bureau of Statistics, 2019). This made it ideal to test the FINDRISC tool in either Swahili or English languages.

3.3 Study Population

The adult population (aged ≥18 years) without known dysglycaemia.

3.4 Eligibility Criteria

3.4.1 Inclusion Criteria

Since FINDRISC was designed to be a self-administered questionnaire, we targeted all individuals of age ≥18 years who were conversant in either English or Swahili language.

3.4.2 Exclusion Criteria

Individuals with the following were excluded from the study:

- History of present or past diagnosis of and/or management for dysglycaemia
- Current use of anti-diabetic drugs regardless of knowledge of dysglycaemia status
- Pregnant women (due to different dysglycaemia diagnostic criteria in this population)
- Physical disability that prevented anthropometric measurements (weight, height, blood pressure or waist circumference)
- Bedridden individuals, since they were likely to be ill and not be reflective of the usual population.

3.5 Sample Size

To determine the minimum sample size required to determine the diagnostic accuracy of FINDRISC for detecting dysglycaemia, we hypothesized that it would demonstrate a discriminatory ability (area under the receiver operating characteristics curve [AUROC]) of 0.7 for any dysglycaemia (Mavrogianni et al., 2019). The minimum sample size required was therefore 328, with α (Type I error) = 5%, β (Type II error) = 20% (Hanley & McNeil, 1982; MedCalc Software Ltd, 2002); based on an expected normoglycaemia-to-dysglycaemia ratio of 94.5:5.5 based on the estimated Kenyan national prevalence of 3.1% and 2.4% for prediabetes and diabetes respectively, 5.5% being the estimated prevalence of dysglycaemia calculated as the sum of the prevalence of prediabetes (3.1%) and diabetes (2.4%) (MOH et al., 2015; Mohamed et al., 2018).

However, a higher minimum sample size of 379 was estimated using the formula below (Cochran 1963, ideal for situations with large populations); 56.3% was used as the proportion expected (P), and the 95% confidence level was used to estimate the prevalence of dysglycaemia in the population without known dysglycaemia within plus or minus 5% of the reported proportion of 56.3%. The proportion expected of 56.3% is the proportion of the Kenyan population that was shown to be unaware its glycaemic condition in 2018 (Mohamed et al., 2018).

$$\mathrm{n} = \frac{\mathrm{Z}_{1-\frac{\mathrm{a}}{2}}{}^{2}}{\mathrm{d2}}\ \chi\, \mathrm{P}(1-\mathrm{P})$$

Where:

$\mathrm{Z}_{1-\frac{\mathrm{a}}{2}}$ =1.96; the quantile of the standard normal distribution corresponding to (1-$^{\alpha}/_{2}$) x100% percentile

α = Type I error, equal to 5%.

P = 56.3% was the prevalence of participants unaware of their glycaemic condition (Mohamed et al., 2018).

d = 5% was the margin of error.

$$\mathrm{n} = \frac{1.96}{0.052}^{2} \times 0.563(1-0.563) = 379$$

The sample size was increased to 422 to cover for an expected non-response rate or missing data for the primary outcome of 10%, as follows:

$$\frac{n}{1-r} = \frac{379}{1-0.1} = 422$$

3.6 Sampling Procedure

Stratified sampling was employed at the screening booths to ensure equitable representation of all age groups in the study population. Five strata based on the age group of potential participants (18-29, 30-44, 45-59, 60-69 and ≥70) formed the basis. Simple random sampling was subsequently employed to randomly select participants from each stratum.

This was done by initially recruiting a subject from each stratum at random and then every k^{th} subject was selected, where *k*, is the sampling interval and calculated as:

$$k = \frac{N}{n}$$

where n is the target sample size, and N is the population size.

Based on patterns observed in preliminary data from ongoing screening in other sites, N was estimated at 461, which was the average individuals screened in each screening site in Kiminini sub-county per month. To achieve a sample size of 422 within 3 months, 141 participants needed to be recruited per month, hence n = 141.

Subsequently, every third participant within each determined age group was invited to participate in the study, provided they met the eligibility criteria, as illustrated below.

$$k = \frac{461}{141} = 3$$

In the case that a randomly selected subject declined participation in the study, or did not meet the eligibility criteria, the next suitable subject (within the age and sex stratum) from the sampling frame was recruited.

3.5 Data Collection

3.5.1 Data Collection Methods

Data was collected via a study instrument, adopted and translated during the pilot phase, and laboratory oral glucose tolerance (OGTT) testing of eligible participants (Appendix D: Oral Glucose Tolerance Test (OGTT) Procedure).

The following measures were also collected from participants using protocols adopted from the FANTA Anthropometric Guide and the 2019 American Heart Association guidelines on measurement of blood pressure in humans (Cashin & Oot, 2018; Muntner et al., 2019) (Appendix E: Anthropometry and Blood Pressure Measurement):

- Body weight (kg)
- Height (m)
- Waist Circumference (cm)
- Systolic blood pressure (SBP) and diastolic blood pressure (DBP)

3.5.2 Adoption and Translation of the Study Instrument

The study instrument was a bilingual (English and Swahili) questionnaire. The English questionnaire consisted of the FINDRISC questionnaire, which was adopted from the original version with minimal modification in language to suit the local setting and to provide local examples borrowed from questions used during the Kenya STEPwise survey of 2015 (MOH et al., 2015), and four additional questions assessing gender, residence (urban versus rural), educational level and employment status. These four factors have previously been investigated for their association with dysglycaemia in Kenya (MOH et al., 2015; Mohamed et al., 2018).

The study instrument was adopted and tranlated through a process of Translation, Review, Adjudication, Pre-testing and Documentation (TRAPD), an approach adapted from (Harkness et al., 2003; International Physical Activity Questionnaire, n.d.). This process was steered by an advisory committee and is illustrated in Figure 2 below.

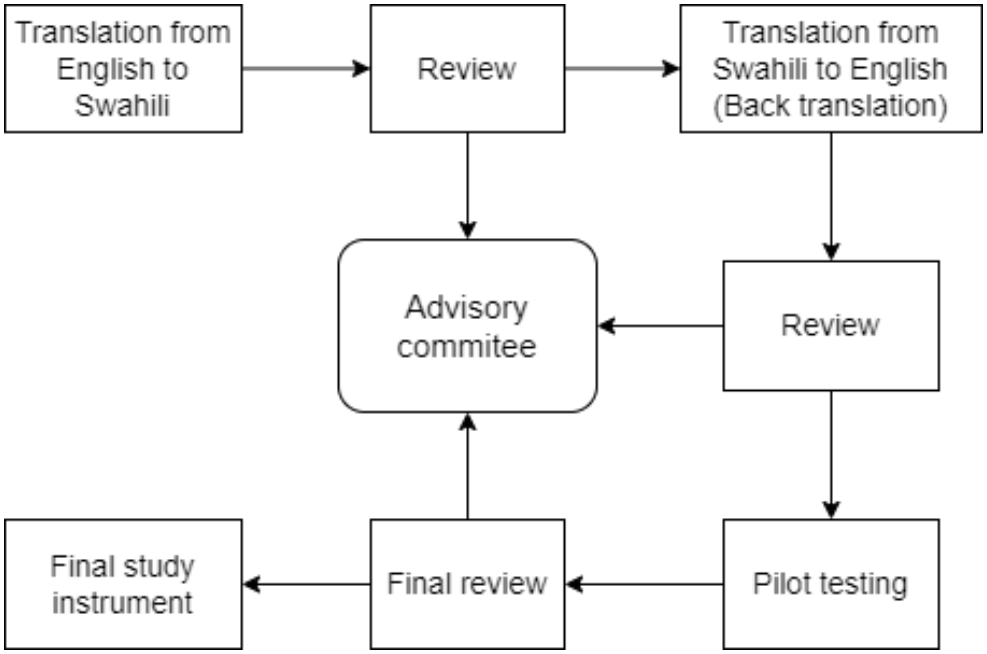


Figure 2: Study instrument development process

Advisory Committee

The first step was to form an advisory committee made up of members conversant with both Swahili and English languages. It was made up of the following individuals:

- An instrument development expert.
- A healthcare provider with experience in caring for diabetic patients and familiar with the local dialect – in this case, a Medical Doctor working in Trans-Nzoia county and overseeing the PIC4C programme in the county was selected.

- One diabetic champion – a Community Health Promoter (CHP) working under the PIC4C programme in Kiminini sub-county.
- Four individuals (2 men and 2 women) selected from the study population, who were also community health volunteers (CHVs) within the study sites.

The objectives of the committee were:

- To review forward translations of the study instrument and determine the wording of the Swahili translation.
- To determine the face and content validity of the study instrument at various phases of development.
- To adjudicate on the final study instrument.

Translation

Two pairs of independent translators were hired; one pair to translate the English questionnaire to Swahili (forward translation), and another pair to translate the Swahili translation back to English (back translation). All translators were experienced in medical research, in addition to the Kenyan culture and dialect. They were provided with a description of the study research aims and objectives, and the study protocol, to help them make more valid translations.

Review

Three reviews were conducted by the advisory committee as depicted in Figure 2 above. Firstly, the committee reviewed the two forward translations; it determined, by consensus, the wording that had the best semantic and conceptual equivalence to the English questionnaire by combining input from both translations to come up with a draft

Swahili questionnaire (Appendix C.4: Final draft Swahili questionnaire). This draft Swahili questionnaire was subsequently forwarded for back translation.

Secondly, the committee reviewed the two back translations (Appendix C.5: Comparison between the final draft Swahili questionnaire, back translations and the Proposed English questionnaire). It determined by consensus that there was adequate semantic and conceptual equivalence to the original English questionnaire. The committee subsequently agreed on and published a draft study instrument comprising the English and draft Swahili questionnaires (Appendix C.6: Final Draft Questionnaire) for subsequent pilot testing.

After the pilot test had been completed, the committee reviewed results from the conducted interviews. It consequently adjudicated on the final study instrument as described below.

Pilot Testing

Cognitive interviews were used to evaluate the draft study instrument. Thirty participants were conveniently sampled from Machungwa region of Kiminini sub-county of Trans-Nzoia during routine community screening that was ongoing within this region. The participants were interviewed and requested to express their feelings towards the study instrument in terms of the following:

- Language clarity
- Appropriateness - whether the questions were culturally appropriate in both language and meaning.
- Difficulty - whether the questions were difficult for them to understand and to respond.

- Relevance - whether the questions, including examples employed, were culturally relevant to their experiences in real-life situations.

They were interviewed as they completed each item as follows:

a. Did you understand all the words?
b. How clear was the intent of the question? (Do you know what is being asked?)
c. Do you have any questions about it?
d. How could the wording be clearer?

At the end of the survey, the following general questions were asked:

a. Did any of the questions make you feel uncomfortable?
b. Were there questions that we missed?

Final Study Instrument

After reviewing data collected from the pilot test, the advisory committee determined that the questionnaire was well understood by the study population during the pilot test. However, it noted that there was a need to qualify the word ‘mboga’ in the Swahili question: “Je, huwa unakula mboga au matunda mara ngapi?’’ to clarify that this question was asking about vegetables and not any food accompaniment. It was decided to include examples of ‘mboga’ into the question. Minor grammatical corrections were also made, and a final study instrument was subsequently adjudicated on (Appendix C.7: Final Study Instrument). This bilingual questionnaire was published in REDCap (Harris et al., 2009, 2019) for subsequent administration via an Android© tablet in the main study.

3.6 Study Procedure

The main study was preceded by the pilot phase that was conducted over a period of 4 weeks in the month of October 2020. Data collection for the main study was done over a period of 15 weeks, from November 2020 to February 2021. The study procedure is summarized in Figure 3.

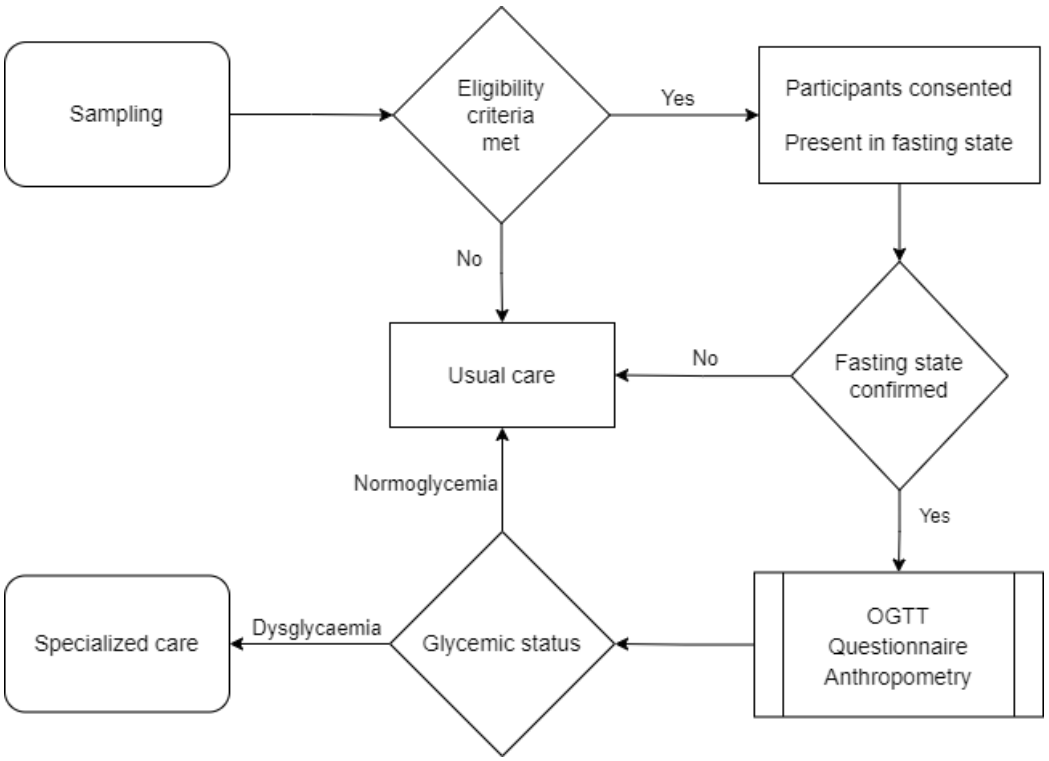


Figure 3: Study procedure

Study participants were recruited via stratified sampling from screening booths within the participating sites as described above. They were invited to present themselves for diagnostic testing within one week at testing sites set up within the catchment areas of the screening booths.

Only participants that met inclusion/exclusion criteria and provided consent were enrolled.

Written informed consent was administered to consenting participants by a research assistant (RA) (Appendix A: Consent Forms). Contact information for subsequent follow up and reminders was also collected.

Prior to diagnostic testing, participants were advised to (Appendix D: Oral Glucose Tolerance Test (OGTT) Procedure):

- Maintain a normal diet (not to change their feeding habits).
- Maintain usual physical activity.
- To fast from 9:00 pm on the night prior to presenting to the testing site.
- Present to the testing site in the morning (between 6:00 am and 9:00 am).

On the testing day, a fasting state was confirmed by enquiring about the time of last meal taken. After confirming a fasting state, the participants were offered an Oral Glucose Tolerance Test (OGTT), as recommended by the World Health Organization (Appendix D: Oral Glucose Tolerance Test (OGTT) Procedure). The 115-minute time frame in between the Fasting Plasma Glucose (FPG) and 2-hour Plasma Glucose (2-hr PG) measurements was utilized to administer the study instrument and to obtain anthropometric measurements (weight, height, waist circumference, SBP and DBP).

Data collected was entered into an Android© tablet containing the study instrument on a REDCap Mobile App.

Blood samples collected were immediately centrifuged after clotting was complete to separate the serum; the serum was then transferred into a cryovial pending transport to Moi Teaching and Referral (MTRH) Reference Laboratory in a cool box for analysis. Serum glucose was estimated via a hexokinase enzyme method using a COBAS INTEGRA® 400 plus analyser (manufactured by Roche Diagnostics).

Results were followed up on the following day for assignment of diagnosis, which was made as follows (MOH, 2018a; WHO & IDF, 2006):

- **Normoglycemia:** Normal blood glucose concentration as follows:
    - FPG <6.1 mmol/l at the beginning of the OGTT, AND
    - 2-hr PG <7.8 mmol/l
- **Prediabetes:** either Impaired Fasting Glucose (IFG), Impaired Glucose Tolerance (IGT), or both as follows:
    - **IFG:** FPG of 6.1–6.9 mmol/l at the beginning of the OGTT
    - **IGT:** 2-hour plasma glucose of 7.8-11.0 mmol/l
- **Diabetes**: FPG ≥7.0 mmol/l or 2-hour plasma glucose ≥11.1 mmol/l, or both

In case of discordance, the worst outcome (diabetes over prediabetes, over normoglycemia) was considered the diagnosis.

Data collected was stored on a REDCap database (Harris et al., 2009, 2019).

3.7 Variables

The independent variables included:

- Age
- Gender
- Education level
- Employment status
- Other FINDRISC test variables: Body mass index, Waist circumference, Physical activity, Dietary consumption of fruits or vegetables, Use of antihypertensive medication, History of high blood glucose, Family history of diabetes

- Systolic and diastolic blood pressure
- OGTT variables: Fasting plasma glucose, 2-hour plasma glucose

The dependent variables included:

- FINDRISC score
- Glycaemic status (Normal, Prediabetes, or Diabetes)

3.8 Data Analysis

Statistical analyses were conducted using R software.

3.8.1 Descriptive statistics

All participants were summarized with respect to demographic characteristics, diabetes risk factors, and FINDRISC score.

Continuous variables such as age, BMI, SBP, DBP, FPG and 2-hr PG were presented as mean (standard deviation) or mean (95% confidence interval), while categorical variables were presented as proportions.

Comparisons between normally distributed continuous variables were performed using Student's t-test. Associations between categorical variables were done using Fisher's exact test.

Statistical tests were two-sided and a p-value of less than 0.05 was considered statistically significant.

3.8.2 Diagnostic accuracy

The following measures of diagnostic accuracy were calculated for various cut-off points of the FINDRISC (0 – 26) for both prediabetes and diabetes:

- Sensitivity
- Specificity
- Positive Predictive Value (PPV)
- Negative Predictive Value (NPV)

Table 2 describes how these measures were determined. The OGTT results were used as the gold standard to define prediabetes and diabetes.

Table 2: Measures of diagnostic accuracy

Outcome of test (FINDRISC)	**Condition (Prediabetes or Diabetes) As determined by the Gold Standard (OGTT)**		**Row Totals**
	Present	**Absent**	
Positive (Meets threshold)	True positive (TP)	False positive (FP)	TP+FP
Negative (< threshold)	False negative (FN)	True negative (TN)	FN+TN
Column totals	TP+FN	FP+TN	TP+FP+FN+TN

- Sensitivity = TP / (TP+FN)
- Specificity = TN / (FP+TN)
- PPV = TP / (TP+FP)
- NPV = TN / (TN+FN)

3.8.3 Discrimination (discriminatory ability)

Discrimination was determined by calculating the area under the receiver operating characteristics curve (AUROC) for both prediabetes and diabetes. The Receiver Operating Characteristics (ROC) curve is a plot that pairs sensitivity and specificity values for every individual cut-off of a diagnostic tool; it is constructed by plotting the true positive rate (sensitivity) on the y-axis against the false positive rate (1-sensitivity) on the x-axis for all FINDRISC cut-off points. As shown in Figure 4, the shape of the ROC curve and the area under the curve (AUROC) helps assess the discriminative

power of a test; the closer the curve is located to upper-left hand (0, 1) point and the larger the area under the curve, the better the test is at discriminating between diseased and non-diseased. The area under the curve of gives a value between 0.5 to 1, a perfect diagnostic test (perfect discrimination) has an AUC 1.0 whereas a non-discriminating test has an area of 0.5.

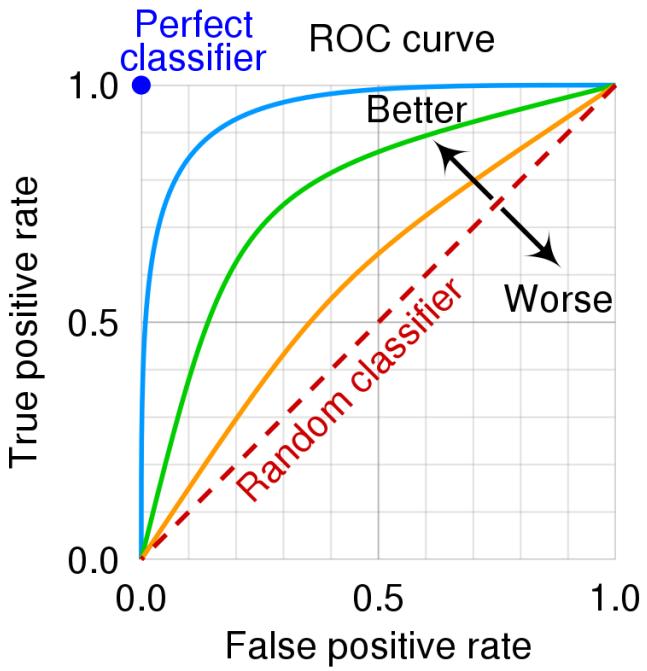


Figure 4: Receiver Operating Characteristic (ROC) curve (Thoma, 2018)

This relationship between AUROC and the discriminatory ability was described as in Table 3 below.

Table 3: Relationship between AUROC and discriminatory ability of a diagnostic test

Area	**Discriminatory ability**
0.9 – 1.0	Excellent
0.8 - 0.9	Very good
0.7 - 0.8	Good
0.6 - 0.7	Sufficient
0.5 - 0.6	Bad
< 0.5	Test not useful

3.8.4 Optimal cut-off points

The optimal cut-off points of FINDRISC (for both prediabetes and diabetes) for the study population were determined by the point with the shortest distance to the (0, 1) point in the ROC curve. This point maximizes the sensitivity and specificity of the test and was calculated as the square root of [(1-sensitivity)2 + (1- specificity)2].

3.8.5 Reporting

Data was reported using prose, tables, and graphs where necessary.

3.9 Ethical Considerations

The following were ensured during the conduct of this study:

- Written informed consent was obtained from each participant to ensure that they took part in the study willingly and without coercion.
- Due to the public health importance of prediabetes and diabetes, all participants were offered health education relevant to their glycaemic and overall health status. This was done via health talks, one-on-one consultation during study participation, and via administration of relevant information pamphlets.
- All participants were informed of their FINDRISC status and advised on the relevance of the same.
- All participants were informed of their blood test results as soon as was feasibly possible and advised on their glycaemic status. All participants discovered to have prediabetes or diabetes were immediately linked to care via a referral form to the nearest health facility of choice.
- Due to the requirement to present on a different day in a fasting state, a token to reimburse transport costs and support participants' breakfast was provided.

- All relevant precautions to prevent spread of COVID-19 were undertaken, including handwashing, sterilization of surfaces and social distancing.
- Participants' data was held in the secure cloud-based storage offered by the REDCap Consortium (Harris et al., 2009, 2019) and was only accessible to the research team. The dataset used for data analysis was also de-identified to further protect participant confidentiality.

Ethical approval was sought from the Institutional Research and Ethics Committee (IREC) at Moi University/Moi Teaching and Referral Hospital (Appendix F: IREC Approval). A research licence was granted by the National Commission for Science, Technology, and Innovation (NACOSTI) (Appendix G: NACOSTI Research License).

Permission to conduct the study in the community was sought via the PIC4C leadership from:

- The Trans-Nzoia County Director of Health.
- The administrative leadership of Trans-Nzoia county, including the County Commissioner, area chiefs and sub-chiefs.
- The respective village elders and *nyumba kumi* chairpersons.

Permission to perform analysis on participants' samples at the MTRH Reference Laboratory was sought from the Deputy Director of Laboratory Services and the Chief Executive Officer (CEO) of MTRH (Appendix F: MTRH Approval).

CHAPTER 4: RESULTS

4.1 Participant Recruitment

As shown in Figure 5, a total of 382 participants completed the study protocol, out of the 422 participants that were enrolled. This represented a 90.5% response rate and met the minimum sample size of 379. Two participants withdrew consent, while 38 failed to turn up for testing.

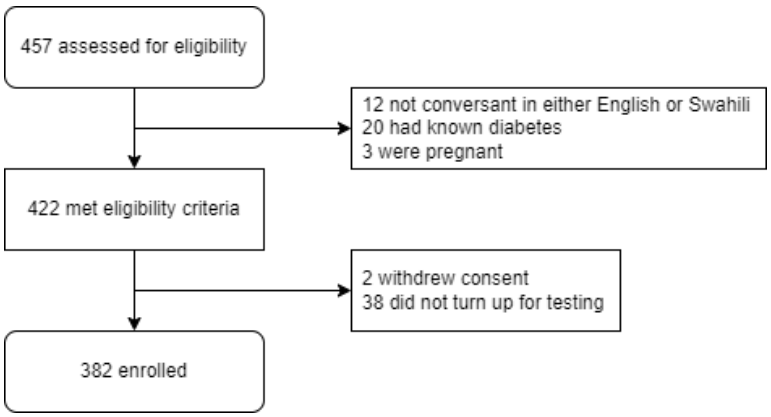


Figure 5: Recruitment schema

4.2 Socio-demographic Characteristics

Table 4 summarizes the socio-demographic characteristics of the study participants. The study population was predominantly rural, with more than ninety per cent of the participants (92.9%) being rural dwellers. The mean age was 45.5 years (95% CI: 43.7 - 47.3), with about half (51%) being aged 18-44 years. There was a predominance of female participants (68%). Literacy level was high with almost ninety per cent of the participants having attained at least primary school education (89.3%); this proportion was significantly higher among male participants (97.6%) than among female participants (85.3%). Most participants (54.7%) were self-employed.

Using Body Mass Index (BMI) to determine obesity, there was a higher proportion of overweight and obesity amongst female participants than male participants (27.1% and 28.3%, versus 17.7% and 3.2% respectively, $P < 0.001$); female participants also had a significantly higher mean BMI than male participants (27.13 kg/m^2 versus 22.49 kg/m^2 respectively, $P < 0.001$). Furthermore, based on waist circumference, female participants were more likely to have abdominal obesity than men (72.1% versus 4%, $P < 0.001$).

The mean blood pressure was in the high normal category (135/86 mmHg) and was similar across male and female participants. Almost thirty five percent (34.6%) of the participants had raised blood pressure (defined as SBP ≥ 140 and/or DBP ≥ 90 mmHg), while almost a fifth of the participants (19.4%) reported to have previously used anti-hypertensives.

On the other hand, a high proportion of study participants reported being physically active, with 76.9% of them reporting to participate in at least 30 minutes of physical activity daily. Male participants were significantly more physically active than female participants (91.1% versus 74%, $P < 0.001$).

The overall prevalence of undiagnosed diabetes and prediabetes was 3.9% (95% CI 1.97% – 5.88%) and 7.9% (95% CI: 5.14 - 10.56) respectively.

The mean FINDRISC score was 7.08; it was lower among male participants compared to female participants (4.18 versus 8.48, $P < 0.001$). The mean fasting blood glucose (FBG) and 2-hour plasma glucose (2-hr PG) were 4.28 mmol/l (95% CI: 4.11 - 4.45) and 5.76 mmol/l (95% CI: 5.45 - 6.08) respectively; they were similar among male and female participants.

Table 4: Socio-demographic characteristics of participants by sex

Characteristic		Male	Female	Total	P value
No (%)		124 (32%)	258 (68%)	382 (100%)	
Age (years)					
Mean (95% CI)		42.85 (39.7 - 46.0)	46.8 (44.6 - 49.0)	45.52 (43.7 - 47.3)	0.05
18-44		73 (58.9%)	122 (47.3%)	195 (51%)	0.2
45-54		3 (2.4%)	9 (3.5%)	12 (3.1%)	
55-64		15 (12.1%)	43 (16.7%)	58 (15.2%)	
65 +		33 (26.6%)	84 (32.6%)	117 (30.6%)	
Education level					
No School		**3 (2.4%)**	**38 (14.7%)**	**41 (10.7%)**	**<0.001**
Primary School		61 (49.2%)	136 (52.7%)	197 (51.6%)	
Secondary School		42 (33.9%)	68 (26.4%)	110 (28.8%)	
Tertiary		18 (14.5%)	16 (6.2%)	34 (8.9%)	
Employment status					
Unemployed		29 (23.4%)	92 (35.7%)	121 (31.7%)	0.012
Self-Employed		**71 (57.3%)**	**138 (53.5%)**	**209 (54.7%)**	
Formally Employed		24 (19.4%)	28 (10.9%)	52 (13.6%)	
Residence					
Rural		**109 (87.9%)**	**246 (95.3%)**	**355 (92.9%)**	0.01
Urban		15 (12.1%)	12 (4.7%)	27 (7.1%)	
BMI (kg/m2)					
Mean (95% CI)		**22.49 (21.54 - 23.43)**	**27.13 (25.04, 26.20)**	**25.62 (25.04 - 26.20)**	**<0.001**
Normal		**98 (79%)**	**115 (44.6%)**	**213 (55.8%)**	**<0.001**
Overweight		22 (17.7%)	70 (27.1%)	92 (24.1%)	
Obese		4 (3.2%)	73 (28.3%)	77 (20.2%)	
Waist circumference (cm)					
Mean (95% CI)		**82.19 (80.04 - 84.39)**	**88.91 (87.42 - 90.41)**	**86.73 (85.46 - 88.00)**	**<0.001**
Male	Female				
<94	<80	108 (87.1%)	68 (26.4%)	176 (46.1%)	**<0.001**
94-102	80-88	11 (8.9%)	4 (1.6%)	15 (3.9%)	
≥102	**≥88**	**5 (4%)**	**186 (72.1%)**	191 (50.0%)	
Blood pressure (BP)					
Systolic BP, Mean (95% CI)		136.0 (132.0 - 140.0)	135.09 (132.4 - 137.8)	135.4 (133.1 - 137.6)	0.714
Diastolic BP, Mean (95% CI)		84.63 (82.4 - 86.9)	87.29 (85.7 - 88.9)	86.43 (85.1 - 87.7)	0.059
Normal		83(66.9%)	167(64.7%)	250(65.4%)	0.731
Elevated (SBP≥140 or DBP≥90mmHg)		41(33.1%)	91(35.3%)	132(34.6%)	
30 min daily physical activity					
No		**11 (8.9%)**	**67 (26%)**	**78 (20.4%)**	**<0.001**
Yes		**113 (91.1%)**	**191 (74%)**	**304 (79.6%)**	
Eats vegetables or fruits					
Not every day		66 (53.2%)	109 (42.2%)	175 (45.8%)	0.049
Every day		58 (46.8%)	149 (57.8%)	207 (54.2%)	
Previous use of anti-hypertensives					
No		**109 (87.9%)**	**199 (77.1%)**	**308 (80.6%)**	**0.013**
Yes		**15 (12.1%)**	**59 (22.9%)**	**74 (19.4%)**	
History of high blood glucose					
No		117 (94.4%)	249 (96.5%)	366 (95.8%)	0.413
Yes		7 (5.6%)	9 (3.5%)	16 (4.2%)	
Family history of diabetes					
No		102 (82.3%)	201 (77.9%)	303 (79.3%)	0.424

Yes (Extended family)	9 (7.3%)	17 (6.6%)	26 (6.8%)	
Yes (Immediate Family)	13 (10.5%)	40 (15.5%)	53 (13.9%)	
FINDRISC score, Mean (SD)	**4.18 (3.77)**	**8.48 (4.72)**	**7.08 (4.86)**	**<0.001**
FBG (mmol/l), Mean (95% CI)	4.41 (4.11 - 4.71)	4.22 (4.01 - 4.43)	4.28 (4.11 - 4.45)	0.306
2-hr PG (mmol/l), Mean (95% CI)	5.79 (5.22 - 6.35)	5.75 (5.37 - 6.14)	5.76 (5.45 - 6.08)	0.918
Glycemic status				
Normal	110 (88.7%)	227 (88%)	337 (88.2%)	0.315
Prediabetes	**7 (5.6%)**	**23 (8.9%)**	**30 (7.9%)**	
Diabetes	**7 (5.6%)**	**8 (3.1%)**	**15 (3.9%)**	

Secondary analysis was also conducted on the socio-demographic data to assess associations between participant characteristics and dysglycaemia; this is summarized in Table B 1. Individuals with dysglycaemia had a higher mean age compared to normoglycemic participants (56.6 years versus 44 years, P <0.001). Dysglycaemia was also significantly associated with higher body mass index (BMI), waist circumference (WC) and blood pressure (BP); previous use of anti-hypertensives, history of high blood glucose and higher FINDRISC class.

4.3 Diagnostic Accuracy of FINDRISC for Undiagnosed Dysglycaemia

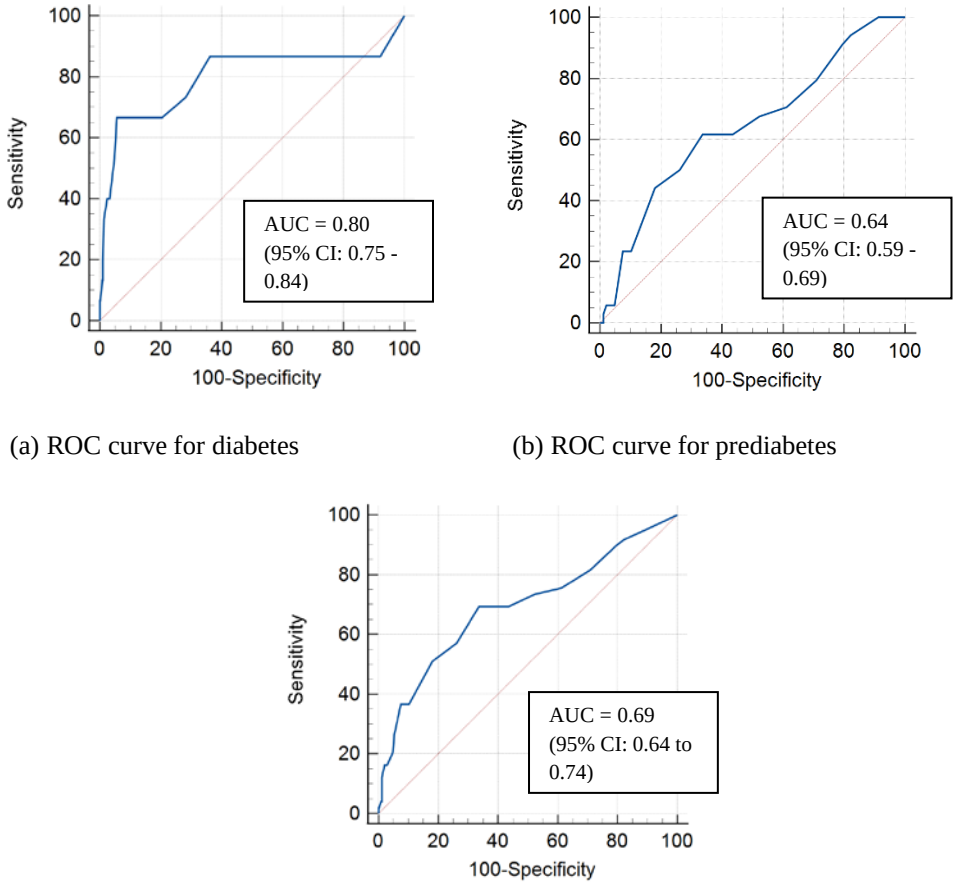
Table B 2 and Figure B 3 summarize the diagnostic accuracy of FINDRISC in identifying individuals with undiagnosed dysglycaemia at various cut-off points. The sensitivity of FINDRSIC for detection of undiagnosed diabetes decreased from 87% at a cut-off point of ≥1 to 7% from a cut-off point of ≥19. Conversely, the specificity increased from 8% at a cut-off point of ≥1 to 100% from a cut-off point of ≥22. The positive predictive value (PPV) ranged from 4% to 100%, while the negative predictive value (NPV) remained high (≥93%) at all cut-off points.

The sensitivity of FINDRSIC for detection of undiagnosed prediabetes decreased from 100% at a cut-off point of ≥1 to 0% from a cut-off point of ≥19. Conversely, the specificity increased from 9% at a cut-off point of ≥1 to 100% from a cut-off point of

≥23. The PPV remained low (≤18%) at all cut-off points, while the NPV remained high (≥92%) at all cut-off points.

The sensitivity of FINDRSIC for detection of both prediabetes and diabetes also decreased from 96% at a cut-off point of ≥1 to 2% from a cut-off point of ≥22. Conversely, the specificity increased from 8% at a cut-off point of ≥1 to 100% from a cut-off point of ≥22. The PPV ranged from 12% to 100%, while the NPV was ≥88% at all cut-off points.

Figure 6 illustrates the receiver operating characteristics (ROC) curves of FINDRISC for detection of undiagnosed dysglycaemia. The area under the curve (AUROC) for detecting undiagnosed diabetes and prediabetes was 0.80 (95% CI: 0.75 - 0.84) and 0.64 (95% CI: 0.59 - 0.69) respectively. The AUROC for the detection of any dysglycaemia (both prediabetes and diabetes) was 0.69 (95% CI: 0.64 to 0.74).



(a) ROC curve for diabetes

(b) ROC curve for prediabetes

(c) ROC curve for both prediabetes and diabetes

Figure 6: The receiver operating characteristics (ROC) curves of FINDRISC for detecting undiagnosed: (a) diabetes, (b) prediabetes, and (c) both prediabetes and diabetes

4.4 Optimal FINDRISC Cut-off Scores for Undiagnosed Dysglycaemia

Table B 3 demonstrates the optimal cut-off scores of the FINDRISC questionnaire for detecting undiagnosed dysglycaemia, determined as the point with the shortest distance to (0,1) on the ROC curve. As highlighted on the table, the optimum cut-off scores for detecting undiagnosed diabetes and prediabetes were ≥14 and ≥10 respectively. The optimum cut-off score for detecting any dysglycaemia (both prediabetes and diabetes) was ≥10.

Table 5 below summarizes the measures of diagnostic accuracy of the optimal cut-off scores of the FINDRISC questionnaire for detecting undiagnosed dysglycaemia.

Table 5: Measures of diagnostic accuracy of optimal FINDRISC cut-off scores for undiagnosed dysglycaemia

Diagnostic Measure	**Diabetes (cut-off ≥14)**	**Prediabetes (cut-off ≥10)**	**Both prediabetes and diabetes (cut-off ≥10)**
	Value (95% CI)	**Value (95% CI)**	**Value (95% CI)**
Sensitivity	0.67 (0.38 - 0.88)	0.57 (0.37 - 0.75)	0.60 (0.44 – 0.74)
Specificity	0.93 (0.90 - 0.96)	0.75 (0.70 - 0.80)	0.77 (0.72 – 0.81)
Positive predictive value	0.29 (0.15 - 0.46)	0.16 (0.10 - 0.25)	0.26 (0.20 – 0.32)
Negative predictive value	0.99 (0.97 - 1.00)	0.95 (0.92 - 0.97)	0.94 (0.90 – 0.95)

CHAPTER 5: DISCUSSION

5.1 Diagnostic Performance of FINDRISC

The Finnish Diabetes Risk Score (FINDRISC) (Lindstrom & Tuomilehto, 2003) is recommended as a pre-screening tool by the International Diabetes Federation (IDF, 2012), as part of selective multistage screening that is recommended for community-based screening for dysglycaemia in resource-constrained settings like Kenya (ADA, 2022; IDF, 2012; WHO, 2003). It has good discriminatory ability in predicting both incident and prevalent diabetes (Abbasi et al., 2012). It is a simple risk calculator that can be conveniently used in primary care and by lay individuals themselves, and is among the most validated diabetes risk scores to date (N. Brown et al., 2012; Mbanya et al., 2015; Noble et al., 2011). Despite being the only non-invasive risk assessment tool that has been extensively evaluated for use in sub-Saharan Africa, including Kenya (Azzouz et al., 2014; Ephraim et al., 2020; Malindisa et al., 2021; Metonnou-Adanhoume et al., 2019; Mugume et al., 2021; Omech et al., 2016; Traoré et al., 2021), it remains unvalidated in a Kenyan pragmatic setting. This study therefore determined its diagnostic performance in a rural community of Western Kenya.

Using oral glucose tolerance test (OGTT) as the reference standard, FINDRISC demonstrated a sensitivity and specificity of 67% (95% CI: 38 – 88%) and 93% (90 – 96%) respectively for the detection of diabetes at an optimal cut-off score of ≥14, with very good discriminatory ability given an estimated area under the receiver operatic characteristics (AUROC) of 0.80 (95% CI: 0.75 - 0.84). This diagnostic performance is similar to its performance among individuals with prevalent diabetes during the 1987 and 1992 FINDRISC model development and internal validation cohorts respectively,

where it demonstrated an AUROC of 0.80 among both populations; the optimum cut-off point for these populations was however lower (≥9) (Lindstrom & Tuomilehto, 2003).

The diagnostic performance of FINDRISC in the study population is also similar to the performance of a modified and simplified FINDRISC questionnaire that demonstrated an AUROC of 0.748 (95% CI: 0.692 – 0.804) and 0.749 (95% CI: 0.692–0.805) respectively for the detection of diabetes in a study utilizing retrospective data of Kenyan adults aged 18-69 years extracted from the 2015 Kenya STEPwise cross-sectional survey (MOH et al., 2015; Mugume et al., 2021). The modified FINDRISC questionnaire excluded the parental/family history of diabetes variable of the original FINDRISC questionnaire but comprised the other FINDRISC questionnaire components (age, BMI, WV, physical activity, fruit and/or vegetable consumption, personal histories of hypertension and diabetes), giving it a maximum score of 20; the simplified FINDRISC questionnaire further excluded the fruit and/or vegetable consumption and physical activity variables, giving it a maximum score of 18 (Mugume et al., 2021). Our findings however demonstrated a higher sensitivity (67%, versus 59.6% and 57.6% for the modified FINDRISC and simplified FINDRSIC questionnaire respectively), and specificity (93%, versus 83.0% and 79.7% for the modified FINDRISC and simplified FINDRSIC questionnaire respectively) at the optimum score of ≥7 for both questionnaires. This suggests that a simplified FRINDRISC questionnaire may be as accurate as the original FINDRISC questionnaire in the Kenyan setting; this is evidenced by the lack of a significant association between dysglycaemia and both fruit and/or vegetable consumption and physical activity among our study population, suggesting that these variables may not have contributed much to the overall accuracy of the FINDRISC questionnaire. Furthermore, exclusion of the family history of

diabetes may be favourable in the Kenyan setting given the fact that a large portion of individuals in Kenya with dysglycaemia remains undiagnosed (Mohamed et al., 2018).

The performance of the FINDRISC questionnaire for detection of diabetes is also similar to its performance in the sub-Saharan African setting of Western Africa (Burkina Faso, Ghana and Benin) where it demonstrated a discriminatory ability of good to very good (Ephraim et al., 2020; Metonnou-Adanhoume et al., 2019; Traoré et al., 2021). However, FINDRISC demonstrated less discriminatory ability in the Southern African population of Botswana (Omech et al., 2016).

In a hospital-based population of Botswana, FINDRISC demonstrated only sufficient discriminatory ability for the detection of diabetes, given an AUROC of 0.63 (95% CI: 0.55 - 0.72), with a sensitivity and specificity of 48% and 73% respectively at an optimum cut-off score of ≥17 (Omech et al., 2016). A possible reason for this performance may have been the use of glycated hemoglobin (HbA1C) as the gold standard test to define diabetes, unlike our study that utilized OGTT; HbA1C has been shown to impair the discriminatory ability of FIDNRISC for detecting type 2 diabetes (Costa et al., 2013). The OGTT is, however, regarded by the World Health Organization (WHO) and International Diabetes Federation (IDF) as the gold standard test for the diagnosis of diabetes (WHO & IDF, 2006) because it is more sensitive than fasting plasma glucose (FPG) and HbA1C (Gavin et al., 1997).

On the other hand, in a cross-sectional study done in the city of Ouagadougou in Burkina Faso, FINDRISC demonstrated a sensitivity and specificity of 70.80% and 62.07% respectively for the detection of type 2 diabetes at an optimum cut-off score of ≥7, with good discriminatory ability, given an AUROC of 0.70 (95% CI: 0.65 – 0.74) (Traoré et al., 2021). Like in the present study, diabetes was defined using OGTT as the

gold standard test for diagnosis and the FINDRISC questionnaire was also adopted to suit the local language.

In another study that utilized retrospective data extracted from a national survey in Benin, FINDRISC demonstrated a sensitivity and specificity of 77% and 89% respectively for the detection of type 2 diabetes at an optimal cut-off score of ≥8.5, with very good discriminatory ability, given an AUROC of 0.86 (95% CI: 0.81 – 0.90) (Metonnou-Adanhoume et al., 2019).

In another Western African setting, FINDRISC demonstrated good discriminatory ability among three fishing communities (Duakor, Ola and Moree) of Cape Coast in the Central Region of Ghana, given an AUROC of 0.76 (95% CI: 0.68 – 0.83); it had a sensitivity and specificity of 58.3% and 86.9% respectively for the detection of type 2 diabetes at an optimal cut-off score of ≥13.5 (Ephraim et al., 2020).

The performance of FINDRISC in the study population also compared favorably with its performance in populations outside sub-Saharan Africa. In a study done among 1000 participants from Algiers in Algeria, FINDRISC demonstrated a sensitivity and specificity of 68% and 64% respectively for the detection of diabetes at an optimum cut-off score of ≥13 and ≥14 in women and men respectively, with sufficient discriminatory ability, given an AUROC of 0.64 (95% CI: 0.60 – 0.68) (Azzouz et al., 2014). Among a multi-racial population of the United States of America, FINDRISC demonstrated an AUROC of 0.75, with a sensitivity and specificity of 72.13% and 65.48% respectively at an optimum cut-off point of ≥11. Other Caucasian populations demonstrated an AUROC of 0.71 – 0.73 with sensitivities of 66 to 81% and specificities of 59.8% to 69% at various cut-off points (≥11 to ≥15) (Makrilakis et al., 2011; Saaristo et al., 2005; Tankova et al., 2011; Zhang et al., 2014).

Table B 4 shows a comparison of the performance of FINDRISC for detection of undiagnosed diabetes between the study populations and the other populations discussed above.

When compared to other screening tests for diabetes, FINDRISC (at a cut-off score of ≥14) demonstrated a sensitivity and specificity similar to the estimated diagnostic performance of both FPG and HbA1C, which are both recommended screening tests for prediabetes and diabetes, for the detection of undiagnosed diabetes, as shown in Table B 5. Fasting plasma glucose was demonstrated to have a summary sensitivity and specificity of 59.4% (95% CI: 46.6 - 71%) and 98.8% (95% CI: 96.5 - 99.6%) respectively for detecting type 2 diabetes in a meta-analysis done to assess the diagnostic accuracy of tests for detecting prediabetes and diabetes within community settings, while an HbA1C cut-off of 6.5% had a summary sensitivity and specificity of 50% (95% CI: 42 – 59%) and 97% (95% CI: 95–98%) respectively in the same meta-analysis (Kaur et al., 2020). This meta-analysis included two studies done in the sub-Saharan setting of South African; one that demonstrated a sensitivity and specificity of 40% (95% CI: 32 – 48%) and 99% (95% CI: 98 – 99%) respectively of FPG at the recommended cut-off of ≥7.0 mmol/l for detecting diabetes (Prakaschandra & Prakesh Naidoo, 2018), and another one that demonstrated a sensitivity and specificity of 70.3% (95% CI: 52.7 – 87.8%) and 98.7% (95% CI: 97.9 – 99.4) respectively of an HbA1C cut-off of ≥6.5% for the detection of diabetes (Hird et al., 2016).

For the detection of undiagnosed prediabetes, FINDRISC demonstrated a sensitivity and specificity of 57% (95% CI: 37 – 75%) and 75% (70 – 80%) respectively in the study population at an optimal cut-off score of ≥10, with a sufficient discriminatory ability, given an AUROC of 0.64 (95% CI: 0.59 - 0.69). This discriminatory ability is similar to

that of both a modified and simplified FINDRISC questionnaire that demonstrated an AUROC of 0.631 (95% CI: 0.576 – 0.685) and 0.636 (95% CI: 0.583–0.688) respectively for detection of undiagnosed prediabetes in a study that utilized retrospective data of Kenyan adults aged 18-69 years extracted from the 2015 Kenya STEPwise cross-sectional survey (MOH et al., 2015; Mugume et al., 2021). It is also similar to its performance among a multiracial study population of the United States of America that demonstrated an AUROC of 0.67, with a sensitivity and specificity of 59.34% and 65.43% respectively at a cut-off point similar to our study population of ≥10 (Zhang et al., 2014). Table B 6 shows a comparison of the performance of FINDRISC for detection of undiagnosed prediabetes among these populations.

The sensitivity and specificity of FINDRISC for detection of undiagnosed prediabetes as a cut-off score of ≥10 in this study population is also similar to that of HbA1C at the cut-off value of 5.7 – 6.4% recommended by the American Diabetes Association for the diagnosis of prediabetes (ADA, 2022), as shown in Table B 7; HbA1C was demonstrated to have a sensitivity and specificity of 50% (95% CI: 39 – 61%) and 75% (95% CI 67 – 81%) respectively for the detection of prediabetes among Africans living in America (Sumner et al., 2016). Other studies report sensitivities ranging from 31.6 to 86.2%, and specificities ranging from 56.3 to 93.3% (Bhowmik et al., 2013; Guo et al., 2014; Kharroubi et al., 2014; Zhou et al., 2009).

When assessed for the detection of both prediabetes and diabetes, FINDRISC demonstrated a sensitivity and specificity of 60% (95% CI: 44 – 74) and 77% (95% CI: 72 – 81) respectively at an optimal cut-off point of ≥10, with a sufficient discriminatory ability, given an AUROC of 0.69 (95% CI: 0.64 to 0.74). It therefore demonstrated a discriminatory ability similar to its discriminatory ability for detection of prediabetes,

with a similar sensitivity and specificity of 60% (44–74) and 77% (72–81) respectively at the same optimal cut-off score of ≥10. A shown in Table B 8, this performance is better than its performance in an urban setting of Mwanza, Tanzania, where FINDRISC demonstrated poor sensitivity and specificity of 39.1% (95% CI: 27.1 - 52.1) and 69.2% (95% CI: 62.2 - 75.6) respectively for detection of dysglycaemia (both prediabetes and diabetes) at a cut-off point of ≥7, with a poor discriminatory ability, given an AUROC of 0.54 (95% CI: 0.47 - 0.61) (Malindisa et al., 2021). Possible reasons for this poor performance included young age of participants (below 45 years of age), which made it difficult to discriminate a risk score based on the age category; need to adopt the questionnaire to a Tanzanian African setting since the types of fruits and vegetables consumed in that population differed compared to the Finnish population; and the fact that ascertaining family history of diabetes mellitus as required in the FINDRISC questionnaire may have been unrealistic since most cases of diabetes mellitus remain undiagnosed due to poor health-seeking habits. The authors recommended the development of a modified (adopted) tool to increase the usefulness of FINDRISC as a pre-screening tool in that setting, similar to what was done in the present study.

Undiagnosed prediabetes and diabetes were present at 7.9% (95% CI: 5.14 - 10.56) and 3.9% (95% CI: 1.97 – 5.88) respectively, higher than the estimated overall age adjusted National prevalence of 3.1% (95% CI: 2.2 - 4.0) and 2.4% (95% CI: 1.8 – 3.0) respectively (MOH et al., 2015; Mohamed et al., 2018). This prevalence is also higher that the estimated National rural prevalence of 2.7% (95% CI: 1.8 - 3.7) and 1.9% (95% CI: 1.3 - 2.5) respectively (MOH et al., 2015; Mohamed et al., 2018). This may be indicative of a high local prevalence of prediabetes and diabetes in rural Western Kenya. Indeed, we observed higher mean body mass index (BMI) [25.62 kg/m^2 (95% CI: 25.04 - 26.20) versus 23.38 kg/m^2 (95% CI:22.95 – 23.81)], waist circumference

(WC) [82.19 cm (95% CI: 80.04 - 84.39) and 88.91 cm (95% CI: 87.42 - 90.41) for males and female respectively versus 78.6 cm (95% CI: 76.7 - 80.4) and 79.1 cm (95% CI: 77.4 - 80.7)] and blood pressure (BP) [135.4/86.43 mmHg (95% CI: 133.1-137.6/85.1-87.7) versus 124.4/80.7 mmHg (95% CI: 123.4-125.4/79.9- 81.4)] compared to the Kenyan national estimates (MOH et al., 2015). Overweight and obesity (defined by BMI), abdominal obesity (defined by WC) and hypertension (high BP) have all been demonstrated to be factors associated with dysglycaemia in Kenya (Chege, 2010; D. L. Christensen et al., 2009; El-Busaidy et al., 2014; Githinji et al., 2017; MOH et al., 2015; Mohamed et al., 2018). When association between demographic characteristics and dysglycaemia was assessed, participants with dysglycaemia (compared to those with normoglycemia) had higher mean BMI, higher mean WC, higher mean BP in addition to a higher mean age (56.6 years versus 44.04 years) and higher proportion of individuals with previous use of anti-hypertensives. This is in addition to a higher proportion of participants with history of high blood glucose and high FINDRISC classes, which have been shown to be predictors of prevalent diabetes (Lindstrom & Tuomilehto, 2003). Like in the FINDRISC model development and internal validation cohorts, both diet and physical activity were not positively associated with dysglycaemia. This trend of a high local prevalence of dysglycaemia and associated risk factors among rural communities has been demonstrated in some studies; Sarah et al. estimated a diabetes prevalence of 15.4% in a rural community of Meru County, Kenya (Sarah et al., 2021), while El-Busaidy et al. estimated a 16% diabetes prevalence rate in Isiolo County (El-Busaidy et al., 2014). The finding of a higher local prevalence of dysglycaemia may therefore also be indicative of a rising prevalence of dysglycaemia in Kenya.

The study population had a female predominance (68%), which is consistent with findings of between 59% - 72% demonstrated in various community-based screening programs conducted within Western Kenya (Nganga et al., 2019; Pastakia et al., 2013; Wachira et al., 2012). Causative factors may include higher rates of healthcare utilization by women (Sikka et al., 2021), or the predominance of a patriarchal society that resulted in men being more likely to be attending to economic activities that caused them to be absent from the home environment at the time of the study (Kenya National Bureau of Statistics, 2014). The latter fact is evidenced by the findings of higher rate of unemployment among female participants from our study population.

Overall, FINDRSISC demonstrated a low positive predictive value (PPV) for the detection of undiagnosed dysglycaemia at all optimal cut-off points, which is expected of predictive models in populations with a low prevalence of the target disease (Florkowski, 2008). This is the case within various populations, Caucasian and African populations alike, where FINDRISC was found to have a PPV < 30% (Ephraim et al., 2020; Malindisa et al., 2021; Metonnou-Adanhoume et al., 2019; Mugume et al., 2021; Omech et al., 2016; Saaristo et al., 2005; Tankova et al., 2011; Traoré et al., 2021; Zhang et al., 2014). This suggests that FINDRISC should not be utilized solely for making a diagnosis of dysglycaemia, rather than as a pre-screening tool as part of a diagnostic strategy to pre-select individuals that would benefit most from definite diagnostic laboratory testing; this strategy is recommended by the WHO and IDF (IDF, 2012; WHO, 2003; WHO & IDF, 2006). The finding of a high negative predictive value (NPV) on the other hand however suggests that individuals that score below the optimal cut-off point may have dysglycaemia reassuringly ruled out (Florkowski, 2008).

The Finnish Diabetes Risk Score (FINDRISC) is therefore a considerably accurate questionnaire that may be considered in this rural population of Western Kenya as a pre-screening tool to exclude individuals with low likelihood of having dysglycaemia from further diagnostic testing. By limiting the number of blood tests required at the screening phase, it has the potential to provide a cheaper and convenient alternative to mass screening using laboratory based diagnostic tests (Khunti et al., 2012) that are currently recommended as the Kenya community screening strategy for dysglycaemia (MOH, 2018a). It can be conveniently used in primary care and also by lay individuals themselves; this is because it utilizes parameters that are easy to assess without any laboratory tests or other clinical measurements requiring special skills (Lindstrom & Tuomilehto, 2003). Since it utilizes known risk factors for dysglycaemia, it also has the potential to increase awareness of the modifiable risk factors for dysglycaemia and promote healthy lifestyles.

5.2 Study Strengths

Dysglycaemia was diagnosed via the Oral Glucose Tolerance Test (OGTT) in strict conformity to the World Health Organization guidelines (WHO, 1985). The OGTT criteria has been shown to be more accurate that other methods, and is the gold standard test recommended by the WHO especially in African populations (WHO & IDF, 2006).

The study population comprised of asymptomatic, community participants, a sub-group of people in which the decision to screen for dysglycaemia is less obvious; this is especially the sub-population for which pre-selection tools like FINDRISC have been recommended by expert groups (ADA, 2022; WHO & IDF, 2006).

This study utilized a pragmatic screening strategy nested within PIC4C, a community-based screening project based in Busia and Trans-Nzoia counties. This provides evidence of the utility of FINDRISC within such settings.

5.4 Study Limitations

Our study population was limited to a rural population residing within Trans-Nzoia county of Western Kenya; it is unclear whether FINDRISC would demonstrate a similar diagnostic performance among other Kenyan populations. However, this limitation is mitigated by the fact that the diagnostic performance of FINDRISC within this study population was similar to its diagnostic performance within a larger, nationally representative study population drawn from the Kenya STEPwise survey of 2015 (Mugume et al., 2021).

The FINDRISC questionnaire was administered in either English or Swahili languages; its utility is therefore limited to literate individuals who understand either of these two languages. However, availability of a Swahili translation is an improvement to the

original FINDRISC questionnaire that only had an English version (Lindstrom & Tuomilehto, 2003). Secondly, Kiminini sub-county wherein this study was conducted, boasts a high level of literacy, with 92.5% and 90.9% of the male and female population respectively having attended at least basic education (Kenya National Bureau of Statistics, 2019); this fact is evidenced by the fact that only 2.9% of participants assessed for eligibility (12 out of 457) failed to be enrolled on the basis of not being conversant in either Swahili or English languages.

CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The Finnish Diabetes Risk Score (FINDRISC) had a high negative predictive value for dysglycaemia.

FINDRISC detected undiagnosed dysglycaemia at an optimal cut-off score of ≥10 using OGTT as the gold standard test to define dysglycaemia.

6.2 Recommendations

FINDRISC should be used as a pre-screening tool to exclude individuals with a low likelihood for dysglycaemia from further diagnostic testing.

Further diagnostic blood testing for dysglycaemia is recommended in subjects with a FINDRISC score of ≥10.

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APPENDICES

Appendix A: Consent Forms

English Version

MOI UNIVERSITY COLLEGE OF HEALTH SCIENCES / MOI TEACHING AND REFERRAL HOSPITAL
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC) INFORMED CONSENT FORM (ICF)

Study Title: Diagnostic Accuracy of the Finnish Diabetes Risk Score (FINSRISC) for Undiagnosed Prediabetes and Diabetes in Western Kenya.

Name of Principal Investigator: Dr Mwangi Muturi

Co Investigators: Dr Jemima Kamano (Supervisor)
Dr Jamil Said (Supervisor)
Dr Juddy Wachira (Supervisor)

Name of Organization: Moi University

Informed Consent Form for: The adult (≥18 years) population residing in Population Health Programme study sites.

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the signed Informed Consent Form

Part I: Information Sheet

Introduction:

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions. If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study. You could still receive other treatments. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that the information provided by you be destroyed under supervision- and thus not used in the research study. You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want to stay in the study.

Purpose of the study:

The purpose of the study is to find out whether a simple questionnaire that has been used in other countries (the FINDRISC questionnaire) can be used in Kenya to predict people likely to have prediabetes and diabetes.

Type of Research Project/Intervention:

This research will make use of a questionnaire in addition to taking a few body measurements and collection of a small amount of blood for diabetes testing.

Why have I been identified to Participate in this study?

You have been selected to participate in this study because you are an adult living in a study site served by the Population Health Programme. This is because the existing programme structures will make it easier for you to participate in this study.

How long will the study last?

The data collection part of this study will last approximately three (3) months.

What will happen to me during the study?

We are asking you to help us learn more about the use of a simple questionnaire to predict whether someone has prediabetes or diabetes. If you accept, you will be asked to provide basic information about yourself by use of a questionnaire. After this, we will request that we take a few body measurements from you (height, weight, waist circumference and blood pressure). You will then be requested to provide a small amount of blood to test for diabetes.

What side effects or risks I can expect from being in the study?

You are likely to experience mild pain/discomfort during drawing of the blood sample. However, due this will be minimized by use of trained professionals and use of the smallest gauge of needle possible for you.

Are there benefits to taking part in the study?

a) The possible benefits to you from this study are the free testing for diabetes. Should we come across a new diagnosis in you, we will refer you to proper care.
b) There are no financial benefits or gifts offered on participation. However, breakfast and transport costs will be reimbursed as described below.
c) The possible benefits to society may include knowledge on the use of pre-screening tools to predict people with pre-diabetes and diabetes in Kenya.

Reimbursements:
You will be offered a sum of sh 150 to reimburse your transport costs and cater for your missed breakfast.

Who do I call if I have questions about the study?
Questions about the study: Dr Mwangi Muturi (Principal Investigator) – 0720 804885

Questions about your rights as a research subject: You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects.

Will the information I provide be kept private?
All reasonable efforts will be made to keep your protected information private and confidential. Protected Information is information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your personal information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, Dr Mwangi Muturi and his study team may share the results of your laboratory tests. These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

- The National Bioethics Committee
- The Institutional Review and Ethics Committee

National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal information private and confidential.

The study results will be retained in your research record for at least six years after the study is completed. At that time, the research information not already in your medical record will be disposed by incineration and permanently deleted from all computer databases containing this information. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your Personal Information does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr Mwangi Muturi in writing and let him know that you are withdrawing your permission. The mailing address is P. O. Box 531 – 10100, Nyeri. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

You have the right to see and copy your personal information related to the research study for as long as the study doctor or research institution holds this information. However, to ensure the scientific quality of the research study, you will not be able to review some of your research information until after the research study has been completed.]

Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part. You will receive a copy of this form after it is signed.

Part II: Consent of Subject:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

_____	_____	_____
Name of Participant (Witness to print if the subject is unable to write	Signature of subject/thumbprint	Date & Time

_____	_____
Name of Representative/Witness	Relationship to Subject

_____	_____	_____
Name of Person Obtaining Consent	Signature of person Obtaining Consent	Date

_____	_____	_____
Printed Name of Investigator	Signature of Investigator	Date

Swahili Version

MOI UNIVERSITY COLLEGE OF HEALTH SCIENCES / MOI TEACHING AND REFERRAL HOSPITAL
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC) INFORMED CONSENT FORM (ICF)

Kichwa: Diagnostic Accuracy of the Finnish Diabetes Risk Score (FINSRISC) for Undiagnosed Prediabetes and Diabetes in Western Kenya.

Jina la Mtafiti Mkuu: Dr Mwangi Muturi

Watafiti Wasaidizi: Dkt Jemima Kamano (Msimamizi)
Dkt Jamil Said (Msimamizi)
Dkt Juddy Wachira (Msimamizi)

Jina la Shirika: Chuo Kikuu cha Moi (Moi University)

Ridhaa ya Taarifa ni kwa: Watu wazima (≥ miaka 18) ambao ni wakazi wa maeneo ambayo yanahusika katika ratiba ya Population Health Programme.

Hii fomu ya ridhaa ya taarifa ina sehemu mbili:

- Karatasi ya Maelezo (ya kukueleza kuhusu utafiti)
- Hati ya Kibali (ishara kuwa umekubali kushiriki kwa utafiti)

Utapewa nakala ya fomu ya ridhaa ya taarifa uliyotia sahihi.

Sehemu ya Kwanza: Karatasi ya Maelezo

Utangulizi:

Unaombwa kushiriki katika utafiti huu na taarifa hii imetolewa kukueleza kuihusu. Tafadhali soma hii fomu kwa makini. Utapatiwa nafasi ya kuuliza maswali. Ikiwa utakubali kushiriki katika utafiti, utapewa nakala ya fomu hii kwa ajili ya rekodi zako.

Kushiriki katika utafiti huu ni kwa hiari yako. Unaweza amua kutoshiriki na bado utaweza kupata matibabu kama kawaida. Kukataa kushiriki haitaathiri haki zako kwa huduma za afya au huduma. Pia uko na uhuru wa kujiondoa kwenye utafiti huu wakati wowote. Unaweza omba kwamba taarifa yoyote uliyoitoa iharibiwe chini ya usimamizi ukiomba kujitoa kutoka huu utafiti, taarifa uliyoitoa haitatumiwa katika utafiti huu. Utatambulishwa kama taarifa mpya inapatikana kuhusu hatari au faida za utafiti huu. Kisha unaweza kuamua kama unataka kuendelea katika utafiti huu.

Sababu ya utafiti:

Sababu ya utafiti huu kujua kama fomu ya maswali ambayo imetumiwa katika nchi zingine (FINDRISC) ina uwezo wa kutumiwa katika nchi ya Kenya kutabiri watu ambao wanaweza kuwa na ugonjwa wa kisukari.

Aina ya Utafiti:

Utafiti huu utatumia fomu ya maswali pamoja na kupima vipimo vya mwili na kuchukua kiasi kidogo cha damu kwa ajili ya kupima ugonjwa wa kisukari.

Kwa nini nimechaguliwa kushiriki katika utafiti huu?

Umechaguliwa kushiriki katika utafiti huu kwa sababu wewe ni mtu mzima (balehe) aliyeishi katika maeneo ambayo yanahusika katika ratiba ya Population Health Programme. Hii ni kwa sababu mifumo zilizowezeshwa na ratiba zitakuwezesha kushiriki virahisi katika utafiti huu.

Utafiti utaendelea kwa muda gani?

Ukusanyaji wa data utaendelea kwa muda wa miezi mitatu (3).

Ni nini kitakachonifanikia katika mchakato wa utafiti huu?

Tunakuomba utusaidie kujifunza zaidi kuhusu matumizi ya fomu ya maswali katika kutabiri kama mtu ako na ugonjwa wa kisukari. Ikiwa unakubali, utaombwa kutoa maelezo ya kimsingi kukuhusu kwa kutumia fomu. Baada ya hayo, tutaomba kwamba tupime vipimo vya mwili (urefu, uzito, mduara wa kiuno na shinikizo la damu). Hatimaye utaombwa kutolewa kiasi kidogo cha damu kwa ajili ya kupima ugonjwa wa kisukari.

Je, ni madhara gani au hatari ambazo ninaweza kutarajia kutoka utafiti huu?

Kuna uwezekano wa uchungu ama usumbufu wakati wa kuchukua sampuli ya damu. Tunatarajia kupunguza huu uchungu ama usumbufu kwa kuajiri wataalamu waliyo na mafunzo ya juu na pia kwa kutumia sindano nyembamba iwezekanavyo.

Je, kuna faida ya kushiriki katika utafiti huu?

a) Faida unayoweza kupata ni kuweza kupata kipimo cha ugonjwa wa kisukari bila malipo. Tukigundua kwamba uko ugonjwa wowote pia tutaweza kukuelekeza kwa matibabu yanayokufaa.
b) Hakuna faida za kifedha ama zawadi zinazotolewa kwa ushiriki wako. Hata hivyo, gharama za kiamsha kinywa na usafiri zitafidiwa.
c) Faida kwa jamii ni ujuzi kuhusu matumizi ya fomu za maswali katika kutabiri watu wenye ugonjwa wa kisukari nchini Kenya

Fidia:
Utapata fidia ya jumla ya shilingi 150 ili kulipa gharama ya usafiri na kuhudumia kiamsha kinywa.

Ninaweza shauri nani kama niko na maswali kuhusu utafiti?
Maswali kuhusu utafiti: Dr Mwangi Muturi (Mtafiti Mkuu) - 0720 804885

Maswali kuhusu haki zako kama mshiriki: Unaweza kuwasiliana na Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC ni shirika linalotathmini utafiti ili kuhakikisha usalama kwa washiriki na kulinda haki zao.

Je, utaweza kuhakikisha faragha ya habari nitayoitoa?
Jitihada zote zitafanywa ili kuhakikisha faragha. Habari inayolindwa ni ambayo imekusanywa kwako, imehifadhiwa na ambayo inaweza kukutambulisha. Utumizi wa habari kama hii lazima ufuate miongozo ya faragha ya kitaifa. Kwa kutia sahihi kwenye hati hii, unatoa idhini kwa watafiti kutumia habari utayoitoa kwa matumizi ya utafiti. Kibali chako cha kushiriki katika utafiti huu una maana kwamba unakubali kuruhusu watafiti kutumia habari hii kwa utafiti wao.

Katika utekelezaji wa utafiti huu, Dkt Mwangi Muturi na timu yake wanaweza shiriki matokeo ya vipimo vya maabara na washika dao wengine. Wanaweza pia kushiriki sehemu za rekodi yako ya matibabu.na:

- The National Bioethics Committee
- The Institutional Review and Ethics Committee

Kanuni za faragha za kitaifa zinaweza kosa kutumiwa kwa vikundi hivi; hata hivyo, wana sera zao na miongozo yao ili kuhakikishia kwamba jitihada zote za busara zitafanywa ili kuweka maelezo yako ya kibinafsi kwa faragha.

Matokeo ya utafiti yatahifadhiwa kwenye rekodi yako ya utafiti kwa angalau miaka sita baada ya utafiti kuisha. Wakati huo ukifika, habari ambayo haiko kwenye rekodi yako itaharibiwa kwa njia ya kuchomwa na itafutwa kwenye orodha zote za kompyuta zilizo na habari hii. Habari yoyote iliyo katika rekodi yako ya matibabu milele.

Hii ruhusa hii ya kutumia au kushiriki habari yako ya kibinafsi haina tarehe ya kumalizika. Ukiaamua kuondoa idhini yako, tunaomba uwasiliane na Dkt. Mwangi Muturi kwa njia ya kuandika na kumjulisha kwamba unaondoa idhini yako. Anwani ya barua ni S. L. P. 531 - 10100, Nyeri. Kwa kufanya hivyo, watafiti watasita kukusanya habari yoyote kukuhusu. Hata hivyo, habari iliyokusanywa kabla ya kuondoa idhini ina uwezo wa kuendelea kutumika katika utafiti kwa madhumuni ya kuripoti na ubora wa utafiti.
Uko na haki ya kupata maelezo kuhusu habari uliyoitoa katika muda ambao watafiti wataendelea kuhifadhi hii habari. Hata hivyo, ili kuhakikisha ubora wa utafiti, kuna uwezekano kwamba hautaweza kupata hii habari hadi baada ya utafiti kukamilika.

Matibabu yako, malipo au usajili katika mipango yoyote ya kiafya ama faida zozote zinginezo haitathiriwa ikiwa utaamua kuondoa idhini. Utapokea nakala ya fomu hii baada ya kuweka sahihi.

Sehemu ya Pili: Hati ya Kibali:

Nimesoma au nimesomewa maelezo ya utafiti huu. Mtafiti mkuu au mwakilishi wake amenielezea utafiti lengo la utafiti huu na amejibu maswali yote niliyo nayo kwa wakati huu. Nimeelezwa kuhusu uwezekano wa hatari, wasiwasi na madhara pamoja na faida iwezekanavyo (kama ipo) ya utafiti. Nimejitolea kwa hiari yangu kushiriki katika utafiti huu.

_____	_____	_____
Jina la Mshiriki (Shahidi aandike kama mshiriki hawezi andika)	Sahihi/Chapa la kidole	Tarehe na Wakati

_____	_____
Jina la Mshahidi	Uhusiano na Mshiriki

_____	_____	_____
Jina la mtu mwenye kuitisha idhini	Sahihi	Tarehe

_____	_____	_____
Jina la Mtafiti	Sahihi	Tarehe

Appendix B: Additional Tables and Figures

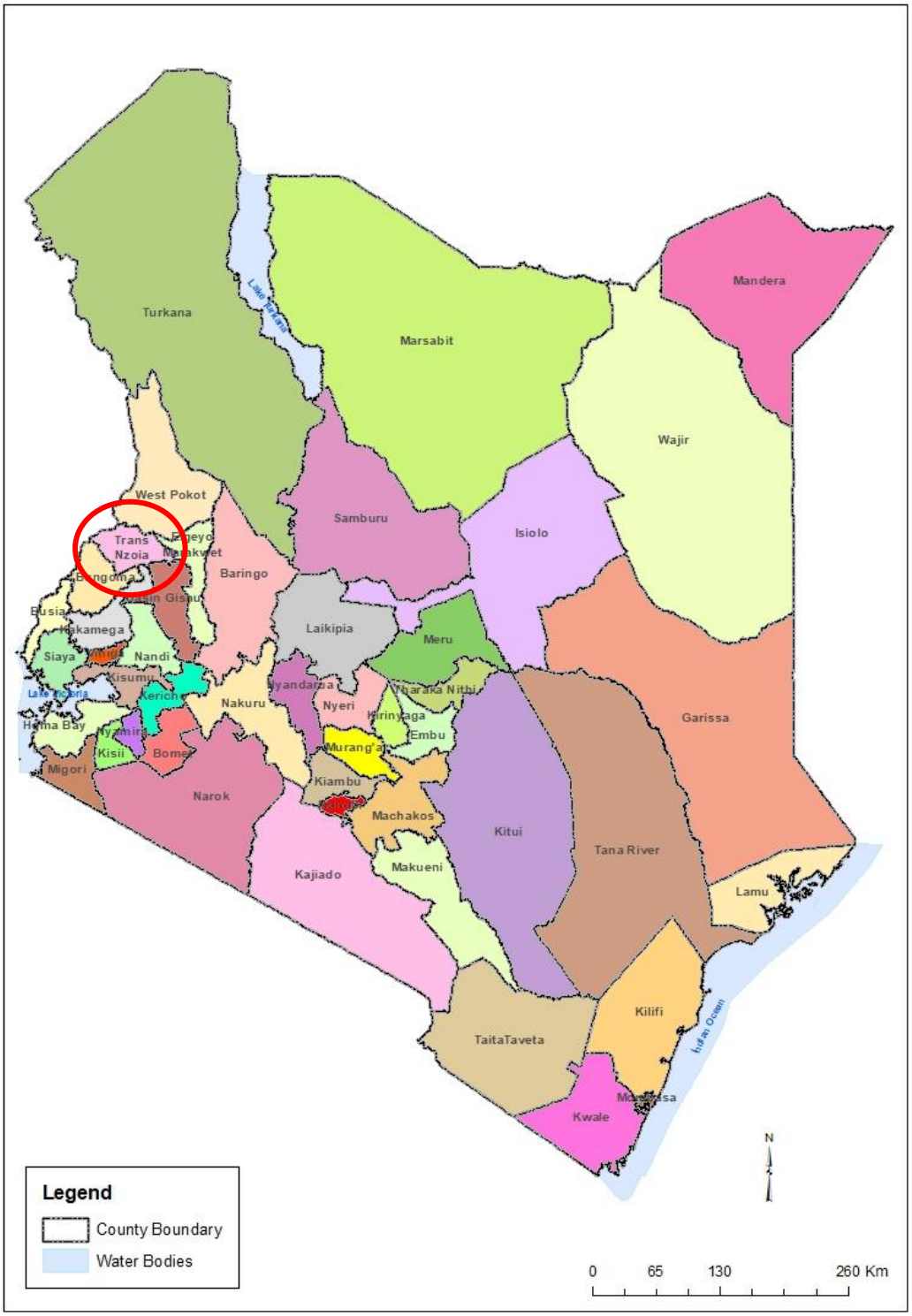


Figure B 1: Counties of Kenya. Source: KNBS. (2019). The 2019 Kenya population and housing census. Nairobi: KNBS.

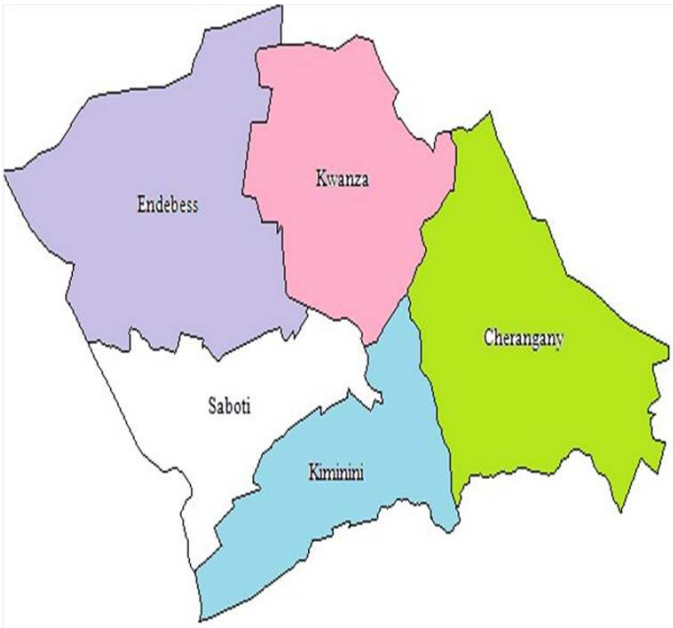


Figure B 2: Sub-counties of Trans-Nzoia county. Source: County Government of Trans-Nzoia. (2020). Trans Nzoia County Annual Development Plan

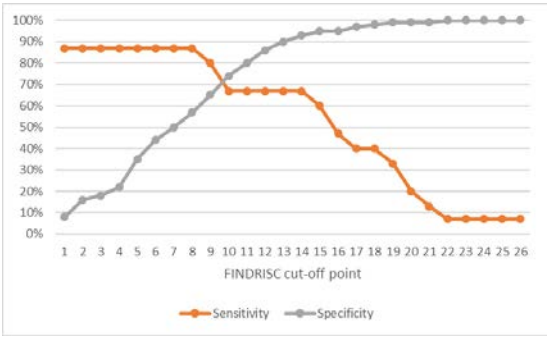
Table B 1: Association between participants' characteristics and dysglycaemia

Characteristic		**Normoglycemia**	**Dysglycaemia**	**P value**
No (%)		337 (88%)	45 (12%)	
Sex				
Male		110 (32.6%)	14 (31.1%)	1
Female		227 (67.4%)	31 (68.9%)	
Age (yrs.)				
Mean (SD)		**44.04 (17.61)**	**56.6 (18.02)**	**<0.001**
Education level				
No School		33 (9.8%)	8 (17.8%)	0.184
Primary School		172 (51%)	25 (55.6%)	
Secondary School		102 (30.3%)	8 (17.8%)	
Tertiary		30 (8.9%)	4 (8.9%)	
Employment status				
Unemployed		104 (30.9%)	17 (37.8%)	0.505
Self-Employed		188 (55.8%)	21 (46.7%)	
Formally Employed		45 (13.4%)	7 (15.6%)	
Residence				
Rural		314 (93.2%)	41 (91.1%)	0.542
Urban		23 (6.8%)	4 (8.9%)	
BMI (kg/m2)				
Mean (SD)		**25.4 (5.66)**	**27.26 (6.27)**	**0.042**
Normal		193 (57.3%)	20 (44.4%)	0.115
Overweight		81 (24%)	11 (24.4%)	
Obese		63 (18.7%)	14 (31.1%)	
Waist circumference (cm)				
Mean (SD)		**85.85 (12.11)**	**93.31 (14.22)**	**<0.001**
Male	Female			
<94	<80	162 (48.1%)	14 (31.1%)	0.089
94-102	80-88	13 (3.9%)	2 (4.4%)	
≥102	≥88	162 (48.1%)	29 (64.4%)	
Systolic BP, Mean (SD)		**133.53 (21.13)**	**149.31 (26.51)**	**<0.001**
Diastolic BP, Mean (SD)		**85.64 (12.51)**	**92.33 (14.41)**	**<0.001**
30 min daily physical activity				
No		69 (20.5%)	9 (20%)	1
Yes		268 (79.5%)	36 (80%)	
Eats vegetables or fruits				
Every day		186 (55.2%)	21 (46.7%)	0.34
Not Every day		151 (44.8%)	24 (53.3%)	
Previous use of anti-hypertensives				
No		**286 (84.9%)**	**22 (48.9%)**	**<0.001**
Yes		**51 (15.1%)**	**23 (51.1%)**	
History of high blood glucose				
No		**333 (98.8%)**	**33 (73.3%)**	**<0.001**
Yes		**4 (1.2%)**	**12 (26.7%)**	
Family history of diabetes				
No		267 (79.2%)	36 (80%)	0.37
Yes (Extended family)		25 (7.4%)	1 (2.2%)	
Yes (Immediate Family)		45 (13.4%)	8 (17.8%)	
FINDRISC Class				
Low (<7)		**174 (51.6%)**	**11 (24.4%)**	**<0.001**
Slightly elevated (7-11)		**120 (35.6%)**	**14 (31.1%)**	
Moderately elevated (12-17)		**27 (8.0%)**	**9 (20.0%)**	
High (≥15)		**16 (4.7%)**	**11 (24.4%)**	

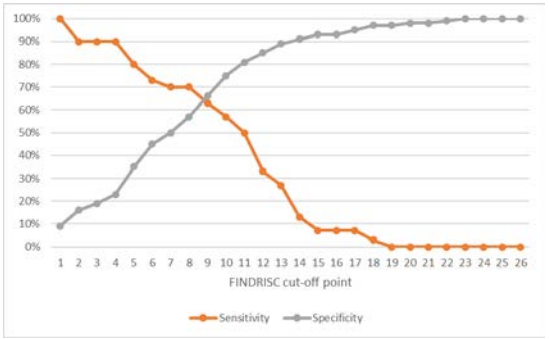
Table B 2: Diagnostic accuracy of FINDRISC for undiagnosed dysglycaemia at various cut-off points

Cut -off	Diabetes				Prediabetes				Both prediabetes and diabetes			
	Se	***Sp***	**PPV**	**NPV**	***Se***	***Sp***	**PPV**	**NPV**	***Se***	***Sp***	**PPV**	**NPV**
≥1	0.87	0.08	0.04	0.93	1.00	0.09	0.09	1.00	0.96	0.08	0.12	0.93
≥2	0.87	0.16	0.04	0.97	0.90	0.16	0.08	0.95	0.89	0.17	0.12	0.92
≥3	0.87	0.18	0.04	0.97	0.90	0.19	0.09	0.96	0.89	0.19	0.13	0.93
≥4	0.87	0.22	0.04	0.98	0.90	0.23	0.09	0.96	0.89	0.23	0.13	0.94
≥5	0.87	0.35	0.05	0.98	0.80	0.35	0.09	0.95	0.82	0.36	0.15	0.94
≥6	0.87	0.44	0.06	0.99	0.73	0.45	0.10	0.95	0.78	0.46	0.16	0.94
≥7	0.87	0.50	0.07	0.99	0.70	0.50	0.11	0.95	0.76	0.52	0.17	0.94
≥8	0.87	0.57	0.08	0.99	0.70	0.57	0.12	0.96	0.76	0.59	0.20	0.95
≥9	0.80	0.65	0.09	0.99	0.63	0.66	0.14	0.95	0.66	0.68	0.22	0.94
≥10	0.67	0.74	0.10	0.98	0.57	0.75	0.16	0.95	0.60	0.77	0.26	0.94
≥11	0.67	0.80	0.12	0.98	0.50	0.81	0.18	0.95	0.56	0.83	0.30	0.93
≥12	0.67	0.86	0.16	0.98	0.33	0.85	0.16	0.94	0.44	0.87	0.32	0.92
≥13	0.67	0.90	0.21	0.99	0.27	0.89	0.17	0.93	0.40	0.91	0.38	0.92
≥14	0.67	0.93	0.29	0.99	0.13	0.91	0.11	0.93	0.31	0.94	0.40	0.91
≥15	0.60	0.95	0.33	0.98	0.07	0.93	0.07	0.92	0.24	0.95	0.41	0.90
≥16	0.47	0.95	0.28	0.98	0.07	0.93	0.08	0.92	0.20	0.95	0.36	0.90
≥17	0.40	0.97	0.33	0.98	0.07	0.95	0.11	0.92	0.18	0.97	0.44	0.90
≥18	0.40	0.98	0.46	0.98	0.03	0.97	0.08	0.92	0.16	0.98	0.54	0.90
≥19	0.33	0.99	0.56	0.97	0.00	0.97	0.00	0.92	0.11	0.99	0.56	0.89
≥20	0.20	0.99	0.43	0.97	0.00	0.98	0.00	0.92	0.07	0.99	0.43	0.89
≥21	0.13	0.99	0.33	0.97	0.00	0.98	0.00	0.92	0.04	0.99	0.33	0.89
≥22	0.07	1.00	0.50	0.96	0.00	0.99	0.00	0.92	0.02	1.00	0.50	0.88
≥23	0.07	1.00	1.00	0.96	0.00	1.00	0.00	0.92	0.02	1.00	1.00	0.88
≥24	0.07	1.00	1.00	0.96	0.00	1.00	0.00	0.92	0.02	1.00	1.00	0.88
≥25	0.07	1.00	1.00	0.96	0.00	1.00	0.00	0.92	0.02	1.00	1.00	0.88
≥26	0.07	1.00	1.00	0.96	0.00	1.00	0.00	0.92	0.02	1.00	1.00	0.88

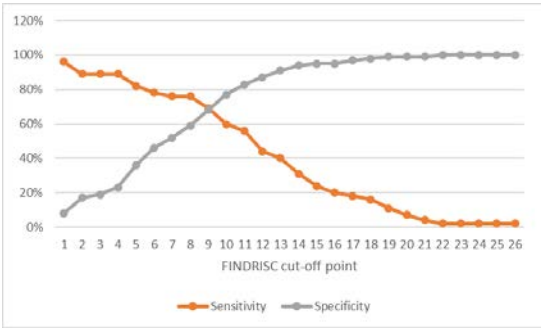
Se = Sensitivity, Sp = Specificity, PPV = Positive Predictive Value, NPV = Negative Predictive Value



(a) Sensitivity and specificity of FINDRISC for detecting diabetes



(b) Sensitivity and specificity of FINDRISC for detecting prediabetes



(c) Sensitivity and specificity of FINDRISC for detecting both prediabetes and diabetes

Figure B 3: Sensitivity and specificity of FINDRISC for undiagnosed (a) diabetes, (b) prediabetes, and (c) both prediabetes and diabetes

Table B 3: Optimum cut-off points of FINDRISC for detection of dysglycaemia

Cut -off	Diabetes			Prediabetes			Both prediabetes and diabetes		
	Se	***Sp***	**Distance to (0,1)**	***Se***	***Sp***	**Distance to (0,1)**	***Se***	***Sp***	**Distance to (0,1)**
≥1	0.87	0.08	0.929	1.00	0.09	0.910	0.96	0.08	0.921
≥2	0.87	0.16	0.850	0.90	0.16	0.846	0.89	0.17	0.837
≥3	0.87	0.18	0.830	0.90	0.19	0.816	0.89	0.19	0.817
≥4	0.87	0.22	0.791	0.90	0.23	0.776	0.89	0.23	0.778
≥5	0.87	0.35	0.663	0.80	0.35	0.680	0.82	0.36	0.665
≥6	0.87	0.44	0.575	0.73	0.45	0.613	0.78	0.46	0.583
≥7	0.87	0.50	0.517	0.70	0.50	0.583	0.76	0.52	0.537
≥8	0.87	0.57	0.449	0.70	0.57	0.524	0.76	0.59	0.475
≥9	0.80	0.65	0.403	0.63	0.66	0.502	0.66	0.68	0.467
≥10	0.67	0.74	0.420	0.57	0.75	0.497	0.60	0.77	0.461
≥11	0.67	0.80	0.386	0.50	0.81	0.535	0.56	0.83	0.472
≥12	0.67	0.86	0.358	0.33	0.85	0.687	0.44	0.87	0.575
≥13	0.67	0.90	0.345	0.27	0.89	0.738	0.40	0.91	0.607
≥14	0.67	0.93	0.337	0.13	0.91	0.875	0.31	0.94	0.693
≥15	0.60	0.95	0.403	0.07	0.93	0.933	0.24	0.95	0.762
≥16	0.47	0.95	0.532	0.07	0.93	0.933	0.20	0.95	0.802
≥17	0.40	0.97	0.601	0.07	0.95	0.931	0.18	0.97	0.821
≥18	0.40	0.98	0.600	0.03	0.97	0.970	0.16	0.98	0.840
≥19	0.33	0.99	0.670	0.00	0.97	1.000	0.11	0.99	0.890
≥20	0.20	0.99	0.800	0.00	0.98	1.000	0.07	0.99	0.930
≥21	0.13	0.99	0.870	0.00	0.98	1.000	0.04	0.99	0.960
≥22	0.07	1.00	0.930	0.00	0.99	1.000	0.02	1.00	0.980
≥23	0.07	1.00	0.930	0.00	1.00	1.000	0.02	1.00	0.980
≥24	0.07	1.00	0.930	0.00	1.00	1.000	0.02	1.00	0.980
≥25	0.07	1.00	0.930	0.00	1.00	1.000	0.02	1.00	0.980
≥26	0.07	1.00	0.930	0.00	1.00	1.000	0.02	1.00	0.980

Table B 4: Performance of FINDRISC for diagnosis of diabetes in various populations

Authors	Study setting	Inclusion criteria	Gold standard, criteria	AUROC (95% CI)	Optimal cut-off point	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
(Muturi et al.)	Kenya	≥18 years	OGTT, WHO	0.80 (0.75 - 0.84)	≥14	67% (38-88)	93% (90-96)	29% (15-46)	99% (97-100)
(Lindstrom & Tuomilehto, 2003)	Finland (Prevalent DM, 1987 cohort)	25-64 years	OGTT, WHO	0.80	≥9	77% (66-85)	66% (64-68)	7% (6-9)	99% (98-99)
(Lindstrom & Tuomilehto, 2003)	Finland (Prevalent DM, 1992 cohort)	25-64 years	OGTT, WHO	0.80	≥9	76% (67-83)	68% (66-70)	12% (10-15)	98% (97-99)
(Mugume et al., 2021)	Kenya, modified FINDRISC	18-69 years	FPG, WHO	0.748 (0.692-0.804)	≥7	59.6%	79.7%	6.9%	98.7%
(Mugume et al., 2021)	Kenya, simplified FINDRISC	18-69 years	FPG, WHO	0.749 (0.692-0.805)	≥7	57.6%	83.0%	7.9%	98.7%
(Omech et al., 2016)	Botswana	≥20 years	HbA1C, ADA	0.63 (0.55-0.72)	≥17	48%	73%	20%	89.5%
(Traoré et al., 2021)	Burkina Faso	18-80 years	OGTT, WHO	0.70 (065-0.74)	≥7	70.80%	62.07%		
(Metonnou-Adanhoume et al., 2019)	Benin	25-65 years	FPG, WHO	0.86 (0.81-0.90)	≥8.5	77%	89%	45%	71%
(Ephraim et al., 2020)	Ghana	52±16 years	FPG, WHO	0.76 (0.61-0.92)	≥13.5	50%	92%		
(Azzouz et al., 2014)	Algeria		OGTT, WHO	0.64 (0.60-0.68)	≥13 (women) ≥11 (men)	68%	64%		
(Zhang et al., 2014)	U.S.A. (Multiracial)	≥20 years	OGTT, ADA	0.75	≥11	72.13%	65.48%		
(Saaristo et al., 2005)	Finland	45-74 years	OGTT, WHO	0.72-men (0.68-0.77)	≥11	66% (58-74)	69% (67-72)	22% (18-26)	94% (92-96)
				0.73-women (0.68-0.78)		70% (61-80)	61% (59-64)	11% (9-14)	96% (95-97)
(Makrilakis et al., 2011)	Greece	35-75 years	OGTT, WHO	0.72 (0.68-0.78)	≥15	81.1%	59.8%	19.3%	96.4%
(Tankova et al., 2011)	Bulgaria	Mean age: 50.3 ± 14.4 years	OGTT	0.71 (0.69-0.73)	≥12	78% (73-85)	62% (58-68)		

Table B 5: Comparison between sensitivity and specificity of FINDRISC and that of FPG and HbA1C for detection of undiagnosed diabetes

Diagnosis criteria	Cut-off	Sensitivity (95% CI)	Specificity (95% CI)
FINDRISC (Muturi et al)	≥14	67% (38 – 88%)	93% (90 – 96%)
FPG (Kaur et al., 2020)	≥7.0 mmol/l	59.4% (46.6 – 71%)	98.8% (96.5 - 99.6%)
FPG (Prakaschandra & Prakesh Naidoo, 2018)	≥7.0 mmol/l	40% (32 – 48%)	99% (98 – 99%)
HbA1C (Kaur et al., 2020)	≥6.5%	50% (42 – 59%)	97% (95 – 98%)
HbA1C (Hird et al., 2016)	≥6.5%	70.3% (52.7 – 87.8)	98.7% (97.9 – 99.4)

Table B 6: Performance of FINDRISC for diagnosis of prediabetes in various populations

Authors	Study setting	Inclusion criteria	Gold standard, criteria	AUROC (95% CI)	Optimal cut-off point	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
(Muturi et al.)	Kenya	≥18 years	OGTT, WHO	0.64 (0.59 - 0.69)	≥10	57% (37-75)	75% (70-80)	16% (10-25)	95% (92-97)
(Mugume et al., 2021)	Kenya, modified FINDRISC	18-69 years	OGTT, WHO	0.631 (0.576-0.685)	≥7				
(Mugume et al., 2021)	Kenya, simplified FINDRISC	18-69 year	OGTT, WHO	0.636 (0.583-0.688)	≥7				
(Zhang et al., 2014)	U.S.A. (Multiracial)	≥20 years	OGTT, ADA	0.67	≥10	59.34%	65.43%	29.4% (20.0-40.3)	77.6% (70.7-83.5)

Table B 7: Comparison between sensitivity and specificity of FINDRISC and that of HbA1C for detection of undiagnosed prediabetes

Diagnosis criteria	Cut-off	Sensitivity (95% CI)	Specificity (95% CI)
FINDRISC (Muturi et al)	≥10	57% (37 – 75%)	75% (70 – 80%)
HbA1C (Sumner et al., 2016)	5.7-6.4%	50% (39 – 61%)	75% (67 – 81%)
HbA1C (Bhowmik et al., 2013)	5.7-6.4%	68.0%	66.4%
HbA1C (Guo et al., 2014)	5.7-6.4%	38.3%	83.4%
HbA1C (Kharroubi et al., 2014)	5.7-6.4%	62.7% (57.1 – 67.9%)	56.3% (53.1 – 59.4%)
HbA1C (Zhou et al., 2009)	5.7-6.4%	59.4%	73.9%

Table B 8: Performance of FINDRISC for diagnosis of both prediabetes and diabetes in various populations

Authors	Study setting	Inclusion criteria	Gold standard, criteria	AUROC (95% CI)	Optimal cut-off point	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
(Muturi et al.)	Kenya	≥18 years	OGTT, WHO	0.69 (0.64-0.74)	≥10	60% (44–74)	77% (72–81)	26% (20–32)	94% (90–95)
(Malindisa et al., 2021)	Tanzania	18-35 years	OGTT, WHO	0.54 (0.47-0.61)	≥7	39.1% (27.1-52.1)	69.2% (62.2-75.6)	29.4% (20.0-40.3)	77.6% (70.7-83.5)

Appendix C: Adoption and Translation of the Study Instrument

Appendix C.1: Original FINDRISC Questionnaire

Finnish Diabetes Association

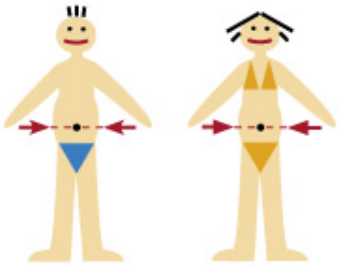
Type 2 diabetes risk assessment form

1. Age
- ☐ Under 45 years (0 p.)
- ☐ 45–54 years (2 p.)
- ☐ 55–64 years (3 p.)
- ☐ Over 64 years (4 p.)

2. Body-mass index
(See reverse of form)
- ☐ Lower than 25 kg/m² (0 p.)
- ☐ 25–30 kg/m² (1 p.)
- ☐ Higher than 30 kg/m² (3 p.)

3. Waist circumference measured below the ribs (usually at the level of the navel)

MEN	WOMEN	
☐ Less than 94 cm	☐ Less than 80 cm	(0 p.)
☐ 94–102 cm	☐ 80–88 cm	(3 p.)
☐ More than 102 cm	☐ More than 88 cm	(4 p.)



4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?
- ☐ Yes (0 p.)
- ☐ No (2 p.)

5. How often do you eat vegetables, fruit or berries?
- ☐ Every day (0 p.)
- ☐ Not every day (1 p.)

6. Have you ever taken medication for high blood pressure on regular basis?
- ☐ No (0 p.)
- ☐ Yes (2 p.)

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?
- ☐ No (0 p.)
- ☐ Yes (5 p.)

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?
- ☐ No (0 p.)
- ☐ Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child) (3 p.)
- ☐ Yes: parent, brother, sister or own child (5 p.)

Total Risk Score

☐

The risk of developing type 2 diabetes within 10 years is

Lower than 7	**Low:** estimated 1 in 100 will develop disease
7–11	**Slightly elevated:** estimated 1 in 25 will develop disease
12–14	**Moderate:** estimated 1 in 6 will develop disease
15–20	**High:** estimated 1 in 3 will develop disease
Higher than 20	**Very high:** estimated 1 in 2 will develop disease

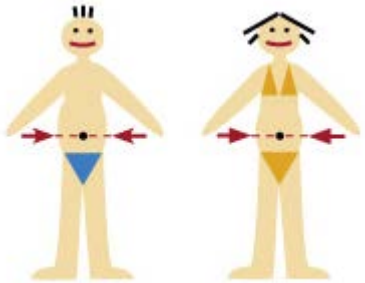
Appendix C.2: Proposed English Questionnaire

Demographic Data

1. Gender: Please tick below.
   - ☐ Female
   - ☐ Male
2. Residence
   - ☐ Rural
   - ☐ Urban
3. Education: What is the highest level of school that you have attended?
   - ☐ Did not attend school
   - ☐ Primary School
   - ☐ Secondary or High School
   - ☐ College/University
4. Employment: What is your current employment status?
   - ☐ Employed (formal employment)
   - ☐ Self-employed (business, farmer etc)
   - ☐ Unemployed

Adapted FINDRISC Questionnaire

1. Age
   - ☐ Under 45 years
   - ☐ 45–54 years
   - ☐ 55–64 years
   - ☐ Over 64 years
2. Body Mass Index (BMI)
   My height is _____ cm
   My weight is _____ kg
   My BMI is:
   - ☐ Lower than 25 kg/m2
   - ☐ 25–30 kg/m2
   - ☐ Higher than 30 kg/m2
3. Waist Circumference Measured Below the Ribs (at the level of the navel)



	Men	Women
☐	Less than 94 cm	Less than 80 cm
☐	94–102 cm	80–88 cm
☐	More than 102 cm	More than 88 cm

4. Do you usually do at least 30 minutes of daily physical activity at work and/or during leisure time? (Including normal daily activity).

   This includes:
   - Time you spend doing work. This includes the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment.
   - The way you travel to and from places e.g., to work, for shopping, to market, to place of worship. This includes time spent spend walking or bicycling for travel on a typical day.
   - Recreational (leisure) activities. This includes moderate-intensity activities e.g., brisk walking, cycling, swimming or volleyball; and high-intensity activities e.g., running or playing football.

   ☐ Yes
   ☐ No
5. How often do you eat vegetables or fruits?
   - ☐ Every Day
   - ☐ Not Every Day
6. Have you ever taken medications for high blood pressure?
   - ☐ No
   - ☐ Yes
7. Have you ever been found to have high blood glucose? (e.g., in a hospital or clinic, during sickness, during pregnancy)
   - ☐ No
   - ☐ Yes
8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes? (Type 1 or type 2)
   - ☐ No
   - ☐ Yes: grandparent, aunt, uncle or first cousin
   - ☐ Yes: parent, brother, sister or own child

Total Risk Score: _____

Key

<7	**Low:** Estimated 1 in 100 will develop disease.
7-11	**Slightly elevated:** Estimated 1 in 25 will develop disease.
12-14	**Moderate:** Estimated 1 in 6 will develop disease.
15-20	**High:** Estimated 1 in 3 will develop disease.
>20	**Very high:** Estimated 1 in 2 will develop disease.

Appendix C.3: Comparison between the proposed English questionnaire and Swahili translations

Proposed English questionnaire	**Swahili translation 1**	**Swahili translation 2**
Demographic Data	**Data (Habari) ya Demografia**	**Takwimu za Idadi ya Watu**
• Gender: Please tick below. □Female □Male	• Jinsia □Kike □Kiume	• Jinsia □Mke □Mme
• Residence □Rural □Urban	• Je, unaishi mashambani au mjini? □Mashambani □Mjini	• Je! Unaishi kijijini au mjini ? □Kijijini □Mjini
• Education: What is the highest level of school that you have attended? □Did not attend school □Primary School □Secondary or High School □College/University	• Je, ni kiwango kipi cha juu cha kielimu umewahi kukikamilisha? □Sikwenda shule □Shule ya Msingi □Shule ya Sekondari au Shule ya Upili □Chuo/Chuo Kikuu	• Je! Umewahi kusoma hadi kiwango gani cha juu? □Sikuhudhuria shule □Shule ya msingi □Sekondari au Shule ya Upili □Chuo/Chuo Kikuu
• Employment: What is your current employment status? □Employed (formal employment) □Self-employed (business, farmer etc) □Unemployed	• Je, hali yako ya sasa ya ajira ni ipi? □Nimeajiriwa (kazi rasmi) □Nimejiajiri mwenyewe (biashara, mkulima n.k.) □Sijaajiriwa	• Aina ya ajira yako ni ipi? □Nimeajiriwa (ajira rasmi) □Nimejiajiri (biashara, ukulima nk) □Sina kazi
Adopted FINDRISC Questionnaire		**Fomu ya takwimu ya FINDRISC**
• Age □Under 45 years □45–54 years □55–64 years □Over 64 years	• Umri □Chini ya miaka 45 □Miaka 45-54 □Miaka 55-64 □Zaidi ya miaka 64	• Umri □ Chini ya miaka 45 □ Miaka 45-54 □ Miaka 55-64 □ Zaidi ya miaka 64
• Body Mass Index (BMI) My height is _____ cm My weight is _____ kg	• Kiwango cha uzito na ukubwa wa mwili (BMI) Kimo (cm) _____ Uzani (kilo) _____	• Kiwango cha uwiano kati ya kimo na uzito ya mwili (BMI) Urefu (cm) _____ Uzito (kilo) _____
• Waist Circumference Measured Below the Ribs (at the level of the navel): _____cm	• Mzingo wa Kiuno - Uliopimwa chini ya mbavu (kwenye kiwango cha kitovu): _____cm	• Mzunguko wa kiuno - (umepimwa chini ya mbavu, kwenye kitovu): _____cm
• Do you usually do at least 30 minutes of daily physical activity at work and/or during leisure time? (Including normal daily activity). This includes: • Time you spend doing work. This includes the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment. • The way you travel to and from places e.g., to work, for shopping, to market, to place of worship. This includes time spent spend walking or bicycling for travel on a typical day.	• Je, huwa unafanya mazoezi ya mwili kwa angalau dakika 30 kila siku ukiwa kazini au wakati wa mapumziko (pamoja na shughuli za kawaida za siku). Hii ni pamoja na: • Muda unaotumia kufanya kazi. Hii ni pamoja na mambo yale ambayo huna budi kuyafanya kama kazi ya kulipwa au isiyolipwa, masomo/mafundisho, kazi za nyumbani, kuvuna chakula/mimea, kuvua samaki au kuwinda kwa ajili ya chakula, kutafuta kazi. • Jinsi unavyosafiri kwenda na kurudi sehemu fulani k.m. kazini, madukani, sokoni, na sehemu za kuabudia. Hii inajumuisha muda unaotumia kutembea au kuendesha baiskeli kwa usafiri kwa siku.	• Je! Wewe hufanya kwa kawaida angalau dakika 30 za mazoezi ya kila siku kazini na / au wakati wa kupumzika? (pamoja na shughuli za kawaida za kila siku). Hii ni pamoja na: • Wakati unaotumia kufanya kazi na mambo ambayo unapaswa kufanya kama kazi ya kulipwa au isiyolipwa, kusoma / mafunzo, kazi za nyumbani, kuvuna chakula / mazao, uvuvi au uwindaji kwa ajili ya chakula, kutafuta ajira. • Jinsi unavyosafiri kwenda kwa mfano kwenda kazini, kwa ununuzi au sokoni, mahali pa ibada. Hii ni

• Recreational (leisure) activities. This includes moderate-intensity activities e.g., brisk walking, cycling, swimming or volleyball; and high-intensity activities e.g., running or playing football. □Yes □No	• Shughuli za burudani (starehe). Hii inajumuisha shughuli nzito za wastani k.m. kutembea haraka, kuendesha baiskeli, kuogelea au voliboli; na shughuli nzito na kali k.m., kukimbia au kucheza kandanda. □Ndiyo □La	pamoja na wakati unaotumia kutembea au kutumia baiskeli kwa kusafiri kwa siku ya kawaida. • Shughuli za burudani. Hii ni pamoja na shughuli za kiwango cha wastani kwa mfano kutembea kwa kasi, kuendesha baiskeli, kuogelea au kucheza mpira wa voleboli; na shughuli za kiwango cha juu mfano, kukimbia au kucheza mpira wa miguu.) □Ndio □La
• How often do you eat vegetables or fruits? □Every Day □Not Every Day	• Je, wewe hula mboga au matunda mara ngapii? □Kila Siku □Si Kila Siku	• Je! Ni mara ngapi unakula mboga au matunda? □Kila Siku □Sio Kila Siku
• Have you ever taken medications for high blood pressure? □No □Yes	• Je, umewahi kutumia dawa za shinikizo la juu la damu? □La □Ndiyo	• Je! Umewahi kuchukua dawa za Shinikizo ya damu? □La □Ndio
• Have you ever been found to have high blood glucose? (e.g., in a hospital or clinic, during sickness, during pregnancy) □No □Yes	• Je, umewahi kupimwa na kupatikana una kiwango kikubwa cha glukosi kwenye damu? (k.m. hospitali au kliniki, wakati wa ugonjwa, wakati wa ujauzito) □La □Ndiyo	• Je! Umewahi kupatikana kuwa na Shinikizo ya damu? (kwa mfano hospitalini au kliniki, wakati wa ugonjwa, wakati wa ujauzito) □La □Ndiyo
• Have any of the members of your immediate family or other relatives been diagnosed with diabetes? (Type 1 or type 2) □No □Yes: grandparent, aunt, uncle or first cousin □Yes: parent, brother, sister or own child	• Je, kuna mtu wa familia yako au hata jamaa amepimwa na kupatikana na (aina ya 1 au aina ya 2) ya kisukari? □La □Ndiyo: babu/nyanya, shangazi, baba mdogo au mkubwa au binamu □Ndiyo: mzazi, ndugu au mwanao	• Je, kuna jamaa wa nyumbani kwako familia au jamaa wengine wamegunduliwa na ugonjwa wa sukari (aina 1 au aina 2)? □La □Ndio: babu, shangazi, mjomba au binamu wa kwanza □Ndio : mzazi, kaka, dada au mtoto wako mwenyewe

Appendix C.4: Final draft Swahili questionnaire

Demografia

- Jinsia
  - ☐ Kike
  - ☐ Kiume
- Je, unaishi mashambani au mjini?
  - ☐ Mashambani
  - ☐ Mjini
- Je, ni kiwango kipi cha juu zaidi cha elimu ambacho umepokea?
  - ☐ Sikuenda shule
  - ☐ Shule ya Msingi
  - ☐ Shule ya Sekondari au Shule ya Upili
  - ☐ Chuo/Chuo Kikuu
- Je, kwa sasa aina ya kazi yako ni gani?
  - ☐ Nimeajiriwa (kazi rasmi)
  - ☐ Nimejiajiri mwenyewe (biashara, mkulima n.k.)
  - ☐ Sijaajiriwa

Orodha ya Maswali ya FINDRISC

- Umri
  - ☐ Chini ya miaka 45
  - ☐ Miaka 45-54
  - ☐ Miaka 55-64
  - ☐ Zaidi ya miaka 64
- Kiwango cha unene (BMI)
  - Urefu (cm) _____
  - Uzito (kilo) _____
- Mzunguko wa Kiuno - Uliopimwa chini kwenye kitovu): _____cm
- Je, kwa kawaida ukiwa kazini ama mapumzikoni, huwa unafanya angalau dakika 30 za mazoezi? Hii inajumuisha shughuli za kawaida za kila siku, kwa mfano:
  - o Kufanya kazi za nyumbani
  - o Shughuli za ukulima
  - o Kutembea/kukimbia
  - o Kuendesha baiskeli
  - o Shughuli za burudani k.m. michezo, mazoezi, au kuogelea
  - ☐ Ndiyo
  - ☐ La
- Je, huwa unakula mboga au matunda mara ngapi?
  - ☐ Kila siku
  - ☐ Sio kila siku
- Je, umewahi kumeza dawa za shinikizo la damu (presha)?
  - ☐ La
  - ☐ Ndiyo
- Je, umewahi kupimwa na kugunduliwa kuwa na kiwango kikubwa cha sukari kwenye damu? (k.m. hospitali/kliniki, wakati wa ugonjwa, wakati wa ujauzito)
  - ☐ La
  - ☐ Ndiyo
- Je, kuna mtu yeyote wa familia yako amewahi kugunduliwa na ugonjwa wa kisukari?
  - ☐ La
  - ☐ Ndiyo: babu/nyanya, shangazi/mjomba, au binamu
  - ☐ Ndiyo: mzazi, ndugu, au mtoto wangu

Appendix C.5: Comparison between the final draft Swahili questionnaire, back translations and the Proposed English questionnaire

Draft Swahili Questionnaire	**Back translation 1**	**Back translation 2**	**Proposed English questionnaire**
Demografia	**Demography**	**Demographics**	**Demographic Data**
• Jinsia □Kike □Kiume	• Gender □Female □Male	• Sex □Female □Male	• Gender: Please tick below. □Female □Male
• Je, unaishi mashambani au mjini? □Mashambani □Mjini	• Do you live in a rural or town area? □Rural □Urban	• Do you live in a rural or urban area? □Rural □Urban	• Residence □Rural □Urban
• Je, ni kiwango kipi cha juu zaidi cha elimu ambacho umepokea? □Sikuenda shule □Shule ya Msingi □Shule ya Sekondari au Shule ya Upili □Chuo/Chuo Kikuu	• What is your highest level of education? □Not gone to school □Primary School □Secondary school or High School □College/University	• What is your highest level of education? □Didn't attend school □Primary School □Secondary school or High School □College/University	• Education: What is the highest level of school that you have attended? □Did not attend school □Primary School □Secondary or High School □College/University
• Je, kwa sasa aina ya kazi yako ni gani? □Nimeajiriwa (kazi rasmi) □Nimejiajiri mwenyewe (biashara, mkulima n.k.) □Sijaajiriwa	• What is your current employment status? □Employed (formal) □Self-employed (business, farmer etc) □Unemployed	• What is your current status of employment? □Employed (formal) □Self-employed (business, farmer etc) □Unemployed	• Employment: What is your current employment status? □Employed (formal employment) □Self-employed (business, farmer etc) □Unemployed
Orodha ya Maswali ya FINDRISC	**FINDRISC Questions**	**FINDRISC List of Questions**	**Adopted FINDRISC Questionnaire**
• Umri □Chini ya miaka 45 □Miaka 45-54 □Miaka 55-64 □Zaidi ya miaka 64	• Age □Under 45 years □45–54 years □55–64 years □Over 64 years	• Age □Under 45 years □45–54 years □55–64 years □Over 64 years	• Age □Under 45 years □45–54 years □55–64 years □Over 64 years
• Kiwango cha unene (BMI) Urefu (cm) _____ Uzito (kilo) _____	• BMI level Height: _____ cm Weight: _____ kg	• Thickness level Height: _____ cm Weight: _____ kg	• Body Mass Index (BMI) My height is _____ cm My weight is _____ kg
• Mzunguko wa Kiuno - Uliopimwa chini kwenye kitovu): _____cm	• Waist Circumference - Taken at the umbilicus: _____ cm	• Waist Circumference - Taken at the navel: _____ cm	• Waist Circumference Measured Below the Ribs (at the level of the navel)
• Je, kwa kawaida ukiwa kazini ama mapumzikoni, huwa unafanya angalau dakika 30 za mazoezi? Hii inajumuisha shughuli za kawaida za kila siku, kwa mfano: o Kufanya kazi za nyumbani o Shughuli za ukulima o Kutembea/kukimbia o Kuendesha baiskeli	• Do you normally do some exercises for at least 30 minutes while at work or during leisure time? This includes your normal daily activities, for example: o Performing house chores o Conducting farming activities o Walking around/jogging o Cycling o Leisure activities e.g., sports, exercise or swimming	• Do you normally exercise for at least 30 minutes while working or relaxing? This includes your normal daily activities, for example: o Doing house chores o Agricultural activities o Walking/running o Riding a bicycle o Recreational activities like sports, exercise or swimming	• Do you usually do at least 30 minutes of daily physical activity at work and/or during leisure time? (Including normal daily activity). This includes: o Time you spend doing work. This includes the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or

o Shughuli za burudani k.m. michezo, mazoezi, au kuogelea □Ndiyo □La	□Yes □No	□Yes □No	hunting for food, seeking employment. o The way you travel to and from places e.g., to work, for shopping, to market, to place of worship. This includes time spent spend walking or bicycling for travel on a typical day. o Recreational (leisure) activities. This includes moderate-intensity activities e.g., brisk walking, cycling, swimming or volleyball; and high-intensity activities e.g., running or playing football. □Yes □No
• Je, huwa unakula mboga au matunda mara ngapi? □Kila siku □Sio kila siku	• How often do you eat vegetables or fruits? □Daily □Not Daily	• How often do you take vegetables or fruits? □Daily □Not Daily	• How often do you eat vegetables or fruits? □Every Day □Not Every Day
• Je, umewahi kumeza dawa za shinikizo la damu (presha)? □La □Ndiyo	• Have you ever taken blood pressure medication (pressure)? □No □Yes	• Have you ever taken hypertension medication (pressure)? □No □Yes	• Have you ever taken medications for high blood pressure? □No □Yes
• Je, umewahi kupimwa na kugunduliwa kuwa na kiwango kikubwa cha sukari kwenye damu? (k.m. hospitali/kliniki, wakati wa ugonjwa, wakati wa ujauzito) □La □Ndiyo	• Have you ever been found to have high blood glucose? (Like hospital/clinic, during illness, during pregnancy) □No □Yes	• Have you ever been tested and found to be diabetic? (Like hospital/clinic, during illness, during pregnancy) □No □Yes	• Have you ever been found to have high blood glucose? (e.g., in a hospital or clinic, during sickness, during pregnancy) □No □Yes
• Je, kuna mtu yeyote wa familia yako amewahi kugunduliwa na ugonjwa wa kisukari? □La □Ndiyo: babu/nyanya, shangazi/mjomba, au binamu □Ndiyo: mzazi, ndugu, au mtoto wangu	• Do you have any family member who was diagnosed of diabetes? □No □Yes: Grandfather / Grandmother, Aunt / Uncle, or Cousin □Yes: Parent, Sibling, or my child	• Has there been any of your family members known to be diabetic? □No □Yes: Grandfather / Grandmother, Aunt / Uncle, or Cousin □Yes: Parent, Sibling, or my child	• Have any of the members of your immediate family or other relatives been diagnosed with diabetes? (Type 1 or type 2) □No □Yes: grandparent, aunt, uncle or first cousin □Yes: parent, brother, sister or own child

Appendix C.6: Final Draft Questionnaire

Demographic Data | Demografia

- Gender
  - ☐ Female
  - ☐ Male
- *Jinsia*
  - ☐ *Kike*
  - ☐ *Kiume*

- Do you live in a rural or urban area?
  - ☐ Rural
  - ☐ Urban
- *Je, unaishi mashambani au mjini?*
  - ☐ *Mashambani*
  - ☐ *Mjini*

- What is your highest level of education?
  - ☐ Did not go to school
  - ☐ Primary School
  - ☐ Secondary or High School
  - ☐ College/University
- *Je, ni kiwango kipi cha juu zaidi cha elimu ambacho umepokea?*
  - ☐ *Sikuenda shule*
  - ☐ *Shule ya Msingi*
  - ☐ *Shule ya Sekondari au Shule ya Upili*
  - ☐ *Chuo/Chuo Kikuu*

- What is your current employment status?
  - ☐ Employed (formal employment)
  - ☐ Self-employed (business, farmer etc)
  - ☐ Unemployed
- *Je, kwa sasa aina ya kazi yako ni gani?*
  - ☐ *Nimeajiriwa (kazi rasmi)*
  - ☐ *Nimejiajiri mwenyewe (biashara, mkulima n.k.)*
  - ☐ *Sijaajiriwa*

FINDRISC Questionnaire | Orodha ya Maswali ya FINDRISC

- Age
  - ☐ Under 45 years
  - ☐ 45–54 years
  - ☐ 55–64 years
  - ☐ Over 64 years
- *Umri*
  - ☐ *Chini ya miaka 45*
  - ☐ *Miaka 45-54*
  - ☐ *Miaka 55-64*
  - ☐ *Zaidi ya miaka 64*

- Body Mass Index (BMI)
  Height: _____ cm
  Weight: _____ kg
- *Kiwango cha unene (BMI)*
  Urefu (cm) _____
  Uzito (kilo) _____

- Waist Circumference - Measured at the level of the umbilicus
  _____ cm
- *Mzunguko wa Kiuno - Uliopimwa chini kwenye kitovu)*
  _____*cm*

- Do you usually do at least 30 minutes of physical activity at work and/or leisure daily?
  This includes normal daily activity, for example:
  - Household chores
  - Farm activities
  - Walking/running
  - Riding a bicycle
  - Recreational activities e.g., playing a sport, gym, or swimming.
  - ☐ Yes
  - ☐ No
- *Je, kwa kawaida ukiwa kazini ama mapumzikoni, huwa unafanya angalau dakika 30 za mazoezi? Hii inajumuisha shughuli za kawaida za kila siku, kwa mfano:*
  - *Kufanya kazi za nyumbani*
  - *Shughuli za ukulima*
  - *Kutembea/kukimbia*
  - *Kuendesha baiskeli*
  - *Shughuli za burudani k.m. michezo, mazoezi, au kuogelea*
  - ☐ *Ndiyo*
  - ☐ *La*

- How often do you eat vegetables or fruits?
  - ☐ Every Day
  - ☐ Not Every Day
- *Je, huwa unakula mboga au matunda mara ngapi?*
  - ☐ *Kila siku*
  - ☐ *Sio kila siku*

- Have you ever taken medications for high blood pressure?
  - ☐ No
  - ☐ Yes
- *Je, umewahi kumeza dawa za shinikizo la damu (presha)?*
  - ☐ *La*
  - ☐ *Ndiyo*

- Have you ever been found to have high blood glucose? (e.g., in a hospital or clinic, during sickness, or during pregnancy)
  - ☐ No
  - ☐ Yes
- *Je, umewahi kupimwa na kugunduliwa kuwa na kiwango kikubwa cha sukari kwenye damu? (k.m. hospitali/kliniki, wakati wa ugonjwa, wakati wa ujauzito)*
  - ☐ *La*
  - ☐ *Ndiyo*

- Have any of your relatives ever been diagnosed with diabetes?
  - ☐ No
  - ☐ Yes: grandparent, aunt, uncle or first cousin
  - ☐ Yes: parent, brother, sister, or own child
- *Je, kuna mtu yeyote wa familia yako amewahi kugunduliwa na ugonjwa wa kisukari?*
  - ☐ *La*
  - ☐ *Ndiyo: babu/nyanya, shangazi/mjomba, au binamu*
  - ☐ *Ndiyo: mzazi, ndugu, au mtoto wangu*

Appendix C.7: Final Study Instrument

Demographic Data | Demografia

- Gender
  - ☐ Female
  - ☐ Male
- *Jinsia*
  - ☐ *Kike*
  - ☐ *Kiume*

- Do you live in a rural or urban area?
  - ☐ Rural
  - ☐ Urban
- *Je, unaishi mashambani au mjini?*
  - ☐ *Mashambani*
  - ☐ *Mjini*

- What is your highest level of education?
  - ☐ Did not go to school
  - ☐ Primary School
  - ☐ Secondary or High School
  - ☐ College/University
- *Je, ni kiwango kipi cha juu zaidi cha elimu ambacho umepokea?*
  - ☐ *Sikuenda shule*
  - ☐ *Shule ya Msingi*
  - ☐ *Shule ya Sekondari au Shule ya Upili*
  - ☐ *Chuo/Chuo Kikuu*

- What is your current employment status?
  - ☐ Employed (formal employment)
  - ☐ Self-employed (business, farmer etc)
  - ☐ Unemployed
- *Je, kwa sasa aina ya kazi yako ni gani?*
  - ☐ *Nimeajiriwa (kazi rasmi)*
  - ☐ *Nimejiajiri mwenyewe (biashara, mkulima n.k.)*
  - ☐ *Sijaajiriwa*

FINDRISC Questionnaire | Orodha ya Maswali ya FINDRISC

- Age
  - ☐ Under 45 years
  - ☐ 45–54 years
  - ☐ 55–64 years
  - ☐ Over 64 years
- *Umri*
  - ☐ *Chini ya miaka 45*
  - ☐ *Miaka 45-54*
  - ☐ *Miaka 55-64*
  - ☐ *Zaidi ya miaka 64*

- Body Mass Index (BMI)
  Height: _____ cm
  Weight: _____ kg
- *Kiwango cha unene (BMI)*
  Urefu (cm) _____
  Uzito (kilo) _____

- Waist Circumference - Measured at the level of the umbilicus
  _____ cm
- *Mzunguko wa Kiuno - Uliopimwa chini kwenye kitovu)*
  _____*cm*

- Do you usually do at least 30 minutes of physical activity at work and/or leisure daily?
  This includes normal daily activity, for example:
  - Household chores
  - Farm activities
  - Walking/running
  - Riding a bicycle
  - Recreational activities e.g., playing a sport, gym, or swimming.
  - ☐ Yes
  - ☐ No
- *Je, kwa kawaida ukiwa kazini ama mapumzikoni, huwa unafanya angalau dakika 30 za mazoezi? Hii inajumuisha shughuli za kawaida za kila siku, kwa mfano:*
  - *Kufanya kazi za nyumbani*
  - *Shughuli za ukulima*
  - *Kutembea/kukimbia*
  - *Kuendesha baiskeli*
  - *Shughuli za burudani k.m. michezo, mazoezi, au kuogelea*
  - ☐ *Ndiyo*
  - ☐ *La*

- How often do you eat vegetables or fruits?
  - ☐ Every Day
  - ☐ Not Every Day
- *Je, huwa unakula mboga (k.m. sukuma wiki, kabeji, kunde, kienyeji) au matunda mara ngapi?*
  - ☐ *Kila siku*
  - ☐ *Sio kila siku*

- Have you ever taken medications for high blood pressure?
  - ☐ No
  - ☐ Yes
- *Je, umewahi kumeza dawa za shinikizo la damu (presha)?*
  - ☐ *La*
  - ☐ *Ndiyo*

- Have you ever been found to have high blood glucose? (e.g., in a hospital or clinic, during sickness, or during pregnancy)
  - ☐ No
  - ☐ Yes
- *Je, umewahi kupimwa na kugunduliwa kuwa na kiwango kikubwa cha sukari kwenye damu? (k.m. hospitali/kliniki, wakati wa ugonjwa, wakati wa ujauzito)*
  - ☐ *La*
  - ☐ *Ndiyo*

- Have any of your relatives ever been diagnosed with diabetes?
  - ☐ No
  - ☐ Yes: grandparent, aunt, uncle or first cousin
  - ☐ Yes: parent, brother, sister, or own child
- *Je, kuna mtu yeyote wa familia yako amewahi kugunduliwa na ugonjwa wa kisukari?*
  - ☐ *La*
  - ☐ *Ndiyo: babu/nyanya, shangazi/mjomba, au binamu*
  - ☐ *Ndiyo: mzazi, ndugu, au mtoto wangu*

Appendix D: Oral Glucose Tolerance Test (OGTT) Procedure

(WHO, 1985)

Preparation

OGTT was administered by a trained laboratory technician, who doubled as a research assistant (RA), in the morning between 6:00 AM and 9:00 AM. Prior to the test, participants had been advised to:

- Continue with an unrestricted diet (greater than 150 g of carbohydrate daily) for at least three days.
- Continue their usual physical activity.
- Fast for at least 8 hours; during this overnight fast, only water could be drunk.
- Not smoke prior to or during the test.

Procedure

1. After confirmation of a fasting state, a 3 ml venous sample was drawn from the participant and transferred into a pre-labelled (participant ID) vacutainer. This was the Fasting Plasma Glucose (FPG) sample.
2. The participant was then offered a drink containing 75 g of glucose in 300 ml of water to drink over the course of 5 minutes. After finishing the drink, a date and time stamp was recorded onto the vacutainer and simultaneously recorded on the laboratory request form.
3. The participant was advised to return within 115 minutes after the time stamp for collection of a second venous sample.
4. After confirmation of the time stamp (within 125 minutes of the FPG sample i.e., 120 -125 minutes) another 3 ml venous sample was drawn from the participant. If a participant presented themselves outside the 125-minute interval, the repeat sample was not drawn; in such a case, the participant's glycaemic state would be based on FPG only.

Blood samples were centrifuged to separate the serum after clotting was complete. Thereafter, the serum was pipetted into a labelled cryovial and stored in a cool box for delivery to the participating laboratory at the end of the day.

Appendix E: Anthropometry and Blood Pressure Measurement

Appendix E.1: Anthropometry

Adapted from the "Guide to Anthropometry" guidelines by the Food and Nutrition Technical Assistance III Project (FANTA) (Cashin & Oot, 2018)

Anthropometric measurements were undertaken by a trained research assistant (RA).

Body Weight

Equipment

A professional standing weighing scale with a valid calibration certificate with an attached heightometer was used to measure weight. It had the following features:

- Able to weigh 0 -150 kg
- Had a precision of 100 g (0.1 kg)

Preparation

1. Verbal consent for weight measurement was obtained from the participant.
2. The scale was placed on a hard, flat (level) surface.
3. The participant was requested to remove his/her shoes, and any heavy clothing; they were left wearing only light clothing during measurement. The participant was also requested to remove anything on his/her head or hair, such as a hat or hair ornament, which may interfere with the length/height measurement.

Procedure

1. The scale was zeroed.
2. The participant was requested to step onto the centre of the scale and to stand still.
3. The RA waited until the weight displayed and remained fixed in the display panel.
4. The RA then informed the participant of his/her weight to the nearest 0.1 kg. He then recorded the participant's weight clearly on the study instrument.
5. A height measurement was then performed using the same instrument as described below.

Height

Equipment

Height was measured using a heightometer attached to the weighing scale. It had the following additional features:

- Able to measure up to 210 cm
- Had a precision of 0.1 cm

Preparation

1. Verbal consent for height measurement was obtained from the participant.
2. The participant was requested to continue standing on the weighing scale.

Procedure

1. The participant was requested to stand in the centre of the weighing scale, with his/her back against the height scale.
2. The RA adjusted the participant's heel to ensure that the "mid-axillary line" (an imaginary line from the tip of the shoulder to the heel) is perpendicular (90°) to the base of the weighing scale where the person is standing.
3. The participant was requested to lift his/her chin so that his/her eyes look straight ahead, making sure that the participant's line of sight (the Frankfort plane) is parallel to the ground and perpendicular (90°) to the back of the weighing scale.
4. The participant was asked to place knees and feet in a natural position, making sure either or both knees and feet touch each other.
5. The RA ensured that:
   - The participant's arms hang down at his/her sides and the shoulders are level.
   - The person's weight is distributed evenly on both feet.
   - The person's buttocks touch the back of the height scale.
6. The participant's position was rechecked and readjusted, as necessary.
7. The RA then gently and firmly slid the heightometer's moveable headpiece down until it touched the crown of the person's head (compresses the hair).
8. The RA informed the participant of the height indicated by the headpiece to the nearest 0.1 cm.
9. The RA then recorded the height on the study instrument.
10. The RA removed the headpiece from the person's head, and gently helped him/her to get off the scale

Waist Circumference

Equipment

A non-elastic measuring tape was used to measure waist circumference. It had a precision of 1 mm (0.1 cm).

Preparation

1. Verbal consent to measure waist circumference was obtained from the participant.
2. The RA showed the measuring tape to the participant. He explained that he will use it to measure the participant's waist and that he will make some markings on the participant's body to ensure that the tape is in the correct position to get an accurate measurement.
3. The RA explained that he must place the tape directly against the skin and asked the participant to adjust her/his clothing (e.g., slightly lower her/his pants and underclothing and slightly lift his/her shirt) so that the umbilicus is showing.

Procedure

1. The RA located the participant's umbilicus.
2. The RA requested the participant to wrap the measuring tape around him/herself and to position the tape at the level of the umbilicus, making sure that the tape is

in the same spot on the opposite side. The tape was meant to be horizontal across the back and front of the person and as parallel as possible to the floor.

3. The RA requested the participant to:
    - Stand erect, with her/his feet positioned close together and his/her weight evenly distributed on both feet.
    - Relax her/his arms at the sides.
    - Breathe out gently and relax while being measured.
4. The RA made sure that the measuring tape is snug but not tight enough to compress the skin. He then bent down to the level of the tape to read the measurement to the nearest 0.1 cm (1 mm).
5. The RA then recorded the waist circumference to the nearest 0.1 cm (1 mm) on the study instrument.

Appendix E.2: Blood Pressure Measurement

Adapted from the 2019 American Heart Association guidelines on the Measurement of Blood Pressure in Humans (Muntner et al., 2019)

Blood Pressure (BP) measurement will be undertaken by a trained research assistant (RA).

Equipment

An Automatic Blood Pressure Machine (Omron M7®) validated for clinical use (El Feghali et al., 2007; Greeff et al., 2009) was used to measure blood pressure. Different cuff sizes for different arm sizes were used to ensure blood pressure accuracy.

Preparation

1. Verbal consent to measure blood pressure was obtained from the participant.
2. The participant was sat on a chair with feet flat on floor and back supported; he/she was allowed to relax for at least 3 min before recording the first BP reading.
3. A quick assessment was done to ensure that the participant has not taken caffeine-containing beverages, exercised, or smoked for the preceding 30 min before measurement.
4. The RA also ensured that the participant had emptied his/her bladder.
5. The RA informed the participant that he/she should not talk during the measurement.
6. Any clothing covering the location of cuff placement was removed.

Procedure

1. The participant’s arm was supported on a desk without the participant holding his/her arm.
2. The middle of the cuff was positioned on the patient’s upper arm at the level of the right atrium (midpoint of the sternum).
3. The correct cuff size (bladder encircles 75%–100% of the participant’s arm) was selected.
4. BP was recorded in both arms; the arm that gave the higher reading was used for subsequent readings.
5. Two repeat measurements were done at least 1 min apart.

6. An average of the 2 last readings was done to estimate the individual's BP (SBP/DBP)
7. The RA then recorded the SBP and DBP onto the study instrument. He also provided the participant with their readings, both verbally and in writing, and helped them interpret the results.

Appendix F: IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2019/000084
Approval Number: 0003568

27th February, 2020

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
27 FEB 2020
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dr. Mwangi Muturi,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Muturi,

DIAGNOSTIC ACCURACY OF THE FINNISH DIABETES RISK SCORE (FINDRISC) FOR UNDIAGNOSED PREDIABETES AND DIABETES IN WESTERN KENYA

This is to inform you that ***MU/MTRH-IREC*** has reviewed and approved your above research proposal. Your application approval number is ***FAN: 0003568.*** The approval period is **27th February, 2020 – *26th February, 2021.***

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MU/MTRH-IREC***.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MU/MTRH-IREC*** within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***MU/MTRH-IREC*** within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to ***MU/MTRH-IREC.***

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix G: MTRH Approval

An ISO 9001:2015 Certified Hospital

MOI TEACHING AND REFERRAL HOSPITAL

Telephone :(+254)053-2033471/2/3/4
Mobile: 722-201277/0722-209795/0734-600461/0734-683361
Fax: 053-2061749
Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
P.O. Box 3 – 30100
ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

3rd March, 2020

Dr. Mwangi Muturi,
Moi University,
School of Public Health,
P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Diagnostic Accuracy of the Finnish Diabetes Risk Score (FINDRISC) for Undiagnosed Prediabetes and Diabetes in Western Kenya".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

MOI TEACHING AND REFERRAL HOSPITAL
CEO
APPROVED
03 MAR 2020
SIGN
P.O. Box 3-30100, ELDORET

03/03/2020

DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

cc - Senior Director, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM

Appendix H: NACOSTI Research License

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 411514

Date of Issue: 07/August/2020

RESEARCH LICENSE

This is to Certify that Dr.. James Mwangi Muturi of Moi University, has been licensed to conduct research in Bungoma, Transnzoia, Uasin-Gishu on the topic: Diagnostic Accuracy of the Finnish Diabetes Risk Score (FINDRISC) for Undiagnosed Prediabetes and Diabetes in Western Kenya for the period ending : 07/August/2021.

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