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COLLEGE OF MEDICINE & HEALTH SCIENCES
SCHOOL OF MEDICIN &PHARMACY

ADHERENCE TO ANTIHYPERTENSIVE MEDICATIONS IN THE PRIMARY CARE SETTING IN RWANDA

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Kigali, March 2020.

DECLARATION

I, Dr. NIYOMWUNGERI Reverien, to the best of my knowledge, hereby declare and certify that the work presented in this dissertation entitled "ADHERENCE TO ANTIHYPERTENSIVE MEDICATIONS IN THE PRIMARY CARE SETTING IN RWANDA." is entirely my own and original work and it has never been presented or submitted in whole or in part to any other University.

Dr. NIYOMWUNGERI Reverien Signature:  Date: 24/07/2020.

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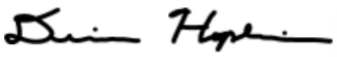
Supervisor:

I, hereby declare that this dissertation has been submitted with my approval as the supervisor.

Dr. Dennis Hopkinson Signature:  Date: 24/07/2020

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Dr. NIYOMWUNGERI Reverien

ABSTRACT

Background

Adherence to long-term medications is a global concern. Hypertension is one of the top five causes of mortality in the world. The asymptomatic nature of this disease results in decreased motivation to adhere to medications that do not provide symptomatic relief in most cases. Poor adherence to long-term medication is a public health concern and causes high costs worldwide. This study determined the degree of adherence to antihypertensive medications in Rwanda and ascertained the causes of lack of adherence.

Methods

This was an observational prospective cohort study conducted at Kigali University Teaching Hospital, Butare University Teaching Hospital, and Kabgayi District hospital. The primary aim was to determine the rate of adherence and the secondary aim was to identify barriers to good adherence if any. A total of 330 patients were enrolled. Data on demographics and social and clinical characteristics were recorded using a questionnaire, and the Self Efficacy for Appropriate Medication use Scale (SEAMS) and Beliefs about Medicines Questionnaire (BMQ) survey instruments were employed to further delve into antihypertensive adherence. The adherence rate was determined through unannounced home visit pill counts. Patients were visited at least on 2 different occasions during 6 months follow up. Good adherence was defined as taking 80% or more of the pills prescribed.

Results

Among 330 participants, 308 (93.3%) completed six months follow up. 78.9% were female and the mean age was 60±12.8 years. The majority (53.4%) had finished primary school. Most participants were married, living with either their spouses or children and take between thirty minutes to one hour to reach the hospital. The rate of good adherence was 88%. Alcohol intake and forgetting to take medication were significant predictors of poor adherence with COR 0.4, 95% CI (0.2-0.8); p=0.021 and COR 5.5, 95% CI (2.7-11.3); p<0.001 respectively. A high Beliefs about Medicines Questionnaire score was associated with good adherence with p=0.009, COR 2.7 95% CI (1.3-5.6). Age, gender, tobacco consumption, or taking more than two medications were not associated with a statistically significant increased risk of poor adherence.

Conclusion

Among patients with hypertension, adherence to antihypertensive medications was good in our setting. Having primary school as the high level of education, forgetting to take medications, alcohol intake, and low Beliefs about Medicines Questionnaire scores were statistically significant predictors of poor adherence but only forgetting to take medications and having primary school as a high level remained statistically significant after multivariate analysis.

Keywords: Hypertension, Medication adherence, Antihypertensive agents, Rwanda.

ACRONYMS

UR/CMHS: University of Rwanda/ College of Medicine and Health Sciences

CHUK/KUTH: Centre Hospitalier Universitaire de Kigali/ Kigali University Teaching Hospital

CHUB/BUTH: Centre Hospitalier Universitaire de Butare/ Butare University Teaching Hospital

IRB: Institutional Review Board

RMH: Rwanda Military Hospital

KFH: King Faisal Hospital

CI: Confidence Interval

OR: Odds Ratio

HIV: Human Immunodeficiency Virus

BMQ: Beliefs about Medicines Questionnaire

HBQ: Hill-Bone Questionnaire

SEAMS: Self-Efficacy for Appropriate Use of Medications Scale

SPSS: Statistical Package for Social Sciences

MMAS-8: 8 item-Morisky Medication Adherence Scale

MoH: Ministry of Health

USA: United States of America.

WHO: World Health Organization.

NCD: Non-Communicable Diseases.

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DEDICATION

To God the Almighty

To my Parents

To my Beloved Wife and Son

To my sisters and brothers

To my relatives and friends

I dedicate this work

Chapter I: Introduction

1.1. Background

Poor adherence to long-term medication is a public health concern and causes high costs worldwide (1)(2). As per the WHO, adherence is defined as "the extent to which a person's behavior—taking medication, following a diet, and, or executing lifestyle changes corresponds with agreed recommendations from a healthcare provider"(3). Compliance with medication is defined as "the extent to which a patient acts per the prescribed interval and dose of the dosing regimen" and is reported as a percentage of prescribed doses taken at the prescribed time interval (4)(5). Despite these variations, these terms have been used interchangeably in most studies, but the clinical practice has shifted away from the term " compliance " now recommending "adherence" to be used to avoid confusion (6)(7). Adherence to medications, especially long-term medications, is an important factor to attain good outcomes(8)(9).

Though hypertension is one of the top five causes of mortality throughout the world (10), nonadherence to antihypertensive is a global burden (3). Good adherence is affected primarily by the asymptomatic nature of the disease (11)(12). The patient generally feels well when untreated, and this can cause a lack of patient motivation to seek care and to adhere to medications (13)(14). The intrinsic motivation to adhere to a medication that makes no discernable difference to the patient's symptoms tends to be lower than medications that treat symptomatic conditions; for example, adherence to medications of other symptomatic diseases in Rwanda such as HIV and tuberculosis tends to be high (approximately 90% for these diseases in some studies) (15)(16)(17).

Therapeutic nonadherence which is defined as not following recommended medical or health advice, including failure to "persist" with medications and recommended lifestyle modifications, is a major contributor to poor control of hypertension and a key barrier to reducing CVD deaths (18). A meta-analysis done in 2017 that evaluated 28 studies, including 6 from Africa, found about 45% of patients were not adherent using MMAS-8 to assess adherence to antihypertensive medications. Nearly two-thirds of non-adherent patients were Africans and Asians, and a higher proportion of patients with uncontrolled hypertension (83.7%) were non-adherent to medications(19).

A study done in Rwanda evaluating barriers to blood pressure control assessed adherence using MMAS-8 and found adherence to be as high as 77% (20) which was higher than most of the other sub-Saharan countries. A study was done in Namibia using a modified Hill-Bone Compliance scale assessing 120 patients found a similar level of adherence to antihypertension medications, with a mean adherence level of 76.7 ± 8.1 % (21).

Different tools to assess adherence to medications have been used (23). Each medication adherence measurement tool (self-report, pill count, medication event monitoring system (MEMS) and electronic monitoring devices, therapeutic drug monitoring, pharmacy records based on pharmacy refill, and pharmacy claims databases) has advantages and disadvantages(23)(24). The direct method which measures the drugs/metabolites levels is accurate and objectively proves the drug was ingested but it is expensive and invasive. This method is also affected by the variation in the pharmacokinetics of drugs, drug-drug, or drug-food interactions, so it is appropriate for measuring adherence to one drug. Pill count is simple, objective, and cheap but there is no evidence the medications were ingested. Besides, pill counts do not provide specific information on daily adherence or patterns on adherence. Questionnaires are standardized, self-reported, easy to use, and inexpensive methods to evaluate adherence but they tend to overestimate adherence and are subject to recall and reporting biases.

At the time of writing this paper, no gold standard has been identified in adherence evaluation and no single method is sufficiently reliable and accurate. A medication events monitoring system device (electronic pillbox) is highly accurate as an objective assessment of medication adherence but is costly (25). While there is no gold standard as to what "good adherence" is, most studies assessing adherence to cardiovascular medications consider an adherence rate of $\geq 80\%$ as good adherence(23)(26). We used the pill count method in this study.

Pill counts measure compliance by comparing the number of doses remaining with the number of doses that should remain. It can provide an accurate measure of compliance when conducted in a patient's home, if the patient is not aware that a pill count is going to be conducted, the dates and amount of medication dispensed are specified, data is available on recent prescription refill and amount leftover from the previous prescription when the current prescription was begun, and whether there was any change in the prescription (27).

In a systematic review assessing adherence to medications of cardiovascular disease in resource-limited settings, pill count was a method using in 16 out of 76 studies overall. In this review, studies evaluating adherence using the pill count method found a slightly higher adherence (62%) than self-report (26).

Adherence is multifactorial and can be influenced by various factors: patient-related (such as knowledge and attitude toward medications), logistic, clinician related, medication-related (such as complex regimen), frequency, and side effect factors all affect adherence(24)(16)(1). A study done in Rwanda found that literacy if the patient had a refill of the last prescription and the hospital where the patient is followed to be the important factors associated with adherence (20). Another study done in Namibia found having family support and attendance of follow-up visits as being significant predictors of good adherence (21). Other factors that have been associated with good adherence include one or no comorbidities, accessibility of medical services, and good patient-care physician interaction (28).

Some studies found adherence to be associated with controlled blood pressure. This was shown in a study performed in South Africa evaluating antihypertensive medication adherence and its determinants at primary healthcare clinics -- adherent patients were twice as likely to have their blood pressure controlled (29). A systematic review and meta-analysis comprised of 28 studies assessing non-adherence to antihypertensive drugs found that compared to controlled hypertensive patients, non-adherence was high (87.3%) in uncontrolled hypertensive patients (30). A cross-sectional study was done in Saudi Arabia evaluating predictors of medication adherence among hypertensive patients attending primary care clinics showed that highly adherent patients (MMAS score = 8) were about five times more likely to have controlled blood pressure compared to low adherent patients(31). Blood pressure control is multifactorial (32)(33), as shown in some studies that good medication adherence is not always associated with good blood pressure control (20)(34). The discordance is thought to be due to the fact that hypertension control has many factors interacting at different levels.

While the asymptomatic nature of hypertension significantly contributes to medication non-adherence, myriad additional factors such as forgetting to take medications, smoking and alcohol intake, beliefs about medications, and others are at play(1)(24). Not only have these factors not been studied in Rwanda, but they also have not been studied extensively in developing countries. Key factors that have been described in studies performed in developing countries include literacy, the high cost of medications, knowledge, beliefs about hypertension, the use of herbal preparations, and irregular follow-up (35).

This study incorporated two validated psychometric adherence tools in one questionnaire: Beliefs about Medicines Questionnaire (BMQ) and Self-Efficacy for Appropriate Medication Use Scale (SEAMS). Like SEAMS, BMQ and HBQ are validated tools that have been developed to assess factors that result in non-adherence to medications (25). More additional questions pertain more to the barriers in developing countries and there is no so-called standard survey (25)(36)(37). When assessing adherence and further understanding the barriers to adherence, these psychometric scales are commonly used. The SEAMS is a valid and reliable 13-item tool that assesses the ability of a patient to take medication as directed, even under difficult circumstances or uncertain conditions (38)(39). The other tool used is Beliefs about Medicines Questionnaire (BMQ) scale. This is comprised of two parts (BMQ-specific and BMQ-general) which can be used separately or in combination (40).

We used BMQ-specific which is a 10-item tool that evaluates patients' beliefs about the necessity of taking prescribed medications to control their disease and concerns about potential adverse events to take it (41)(42). The participants indicate their level of agreement (strongly disagree = 1 to strongly agree = 5) on each of the 5 statements. The total scores are summed, with a high score indicating high beliefs (necessity). Both of these tools are valid and have been used to assess adherence and barriers in patients with chronic illnesses taking long-term medications (36).

Given the rise in the prevalence of non-communicable disease in Rwanda, it is of the utmost importance to understand the rate at which patients are adhering to their antihypertensive medications; moreover, it is necessary to understand why patients do not adhere when this is the case by assessing barriers to good adherence. Determining the rate of adherence will serve to assess the gravity of the issue. Seeking the factors that result in lack of adherence will allow for the development of initiatives to improve adherence to medications that treat chronic disease in Rwanda. This proposed study will seek to determine the degree of adherence to antihypertensive medications in Rwanda and will ascertain the causes of lack of adherence when it occurs.

1.2. Problem statement

Poor adherence to antihypertensive medications contributes strongly to long-term complications including cerebrovascular accidents, heart failure, and coronary artery disease (43)(44).
This study aims to determine if the lack of good adherence exists in the Rwandan population and to explore the barriers behind this poor adherence. Knowing all these barriers, in future work, we will be able to tackle each in advance to prevent all the above-cited complications of poorly treated hypertension.

1.3. Hypothesis:

We hypothesized that patients with Hypertension followed at NCD Clinic at Kabgayi, CHUB and CHUK have poor adherence. Additionally, factors that may contribute to non-adherence are thought to be a high cost of medications, lack of knowledge about hypertension and its possible consequences, and complex medication regimens for patients with comorbidities.

1.4. Objectives

1.4.a. Main objective

This project aims to determine the rate of adherence to antihypertensive medications and barriers to adherence in the primary care setting through survey and direct measure (manual pill count with unannounced home visits) methodologies.

1.4.b. Specific objectives

- To determine the rate of adherence to antihypertensive medications
- To determine the barriers to adherence to antihypertensive medications in primary care settings in Rwanda.

Chapter II: Methodology

2.1. Study type.

An observational prospective cohort study

2.2. Study setting.

Internal medicine non-communicable disease clinics at University Teaching Hospital of Kigali (CHUK), University Teaching Hospital of Butare (CHUB), and District Hospital Kabgayi.

2.3. Population.

The study recruited patients with hypertension on medication therapy who are followed in Kabgayi District Hospital, Butare University Teaching Hospital (CHUB), and Kigali University Teaching Hospital (CHUK) from June 2019 - November 2019.

2.4. Inclusion criteria

- Patients 18 years old or greater who have been diagnosed with hypertension
- Willing and able to consent to participate in the survey and to unannounced home visits

2.5 Exclusion criteria

- Hypertensive patients not taking medications
- Pregnant women
- Prisoners

2.6. Sample size of the study

The sample size was calculated using the prevalence sample size formula, using the prevalence from the study done previously from one of our study settings by simple random sampling.

Sample size=n= $\frac{Z^2 P(1-P)}{D^2}$

Where:

n: minimal sample size required

Z: Score corresponding to the level of confidence with which it is desired to be sure that the true population lies with $\pm D$ percentage points of the sample estimate otherwise noted assume 2-sided test with z=1.96.

P: expected population proportion otherwise noted from the published previous study, assume p=0.5 to obtain the most conservative estimate for n; here p was 0.77 from the published study in Rwanda (20).

D: Precision or absolute error (at p=0.05).

The calculated minimum sample size in this study was 272 participants.

For the survey, 330 participants were recruited: 100 patients at Kabgayi District Hospital,147 from CHUK, and 83 from CHUB.

2.7. Survey design and sampling strategy

Trained medical students helped the participants to complete the surveys and gave explanations when needed. A survey (questionnaire) was created and had four sections. The first section included questions related to sociodemographic data and clinical characteristics. The second part contained questions assessing self-efficacy for taking medications using the SEAMS scale to assess adherence to medications. The third part was based on BMQ (Beliefs about Medication Questionnaire) scale. The fourth part included antihypertensive medications prescribed, the number of pills prescribed per month, frequency, and dosing.

The questionnaire (Kinyarwanda version) was first piloted with 7 patients in out-patient clinics and subsequently was modified to improve comprehensibility. The surveys were administered by trained medical students. Patients with hypertension who attended the above-specified clinics were approached at random during outpatient clinic days during the study period.

The study was described to patients or legal representatives in terms of the reasons for the study, the rights to withdraw, and the benefits of the study. If the patients agreed on participating in the study, they were taken to a private room where written informed consent was sought and signed, and the patients completed the survey. Written consent in Kinyarwanda or English was provided to participants or surrogates to be signed or use a thumbprint for patients who do not sign. After the explanation, both the patient and the investigator signed the consent form (Annex).

The Principle Investigator (PI) created a dataset key and assigning a unique identifier to each enrolled patient for recording individual patient study data. The resultant study data from paper-based surveys were locked in cabinets under the PI's custody. Thereafter, these data were de-identified and then stored electronically in password-protected files on an encrypted computer in REDCap. The PI was responsible for overseeing data management.

2.8. Data collection procedure

Participants' data including contacts, location, socio-demographics, clinical characteristics were first collected on paper-based questionnaires. They were then entered into REDCap, a secure online platform to safeguard the data. Every patient was assigned a code to identify them to maintain their confidentiality. At the time of the unannounced home visits, we had to briefly call the patients or their relatives ahead of time to check if they were at home and asked the exact location of their home. We requested the patients to provide their medications with the prescription papers to check the dates. We determined when the patient had collected the last prescription and when they took the first dose, the dosage, and the frequency of the medication. For the once-daily doses, we asked them to specify if they take them in the morning or evening time.

Manual pill count was done, the total number of pills for the full prescription dose was documented, and the remaining pills were recorded as well. The difference was calculated to determine the number of pills taken versus the number of pills the patient should have taken. The information regarding the date of last prescription, date of starting first doses, number of remainders, number of pills a patient was supposed to take was then completed on a paper-based survey, then entered into REDCap with confidentiality measures as above mentioned. No incentives were given to participants.

2.9. Data analysis

Collected data were entered into Epidata version 3.1 for database creation and then exported to SPSS version 25 for analysis. Descriptive data are presented as follows: categorical data are presented using frequencies and percentages in tables and charts as applicable and continuous data are summarized by mean and median values depending on their distributions. Chi-square test and linear logistic regression (binary logistic regression) were used to study the relationship between the outcomes and possible predictors. Statistical significance for associations was taken at the level $p < 0.05$ with a confidence interval of 95%.

2.10. Ethical considerations

Ethical approval was obtained from the University of Rwanda/ School of Medicine through the Institutional Review Board (Nº 379/CMHS IRB/2018). Approvals forms were also sought from the University Teaching Hospital of Kigali Ethic committee (EC/CHUK/020/2019) and the University Teaching Hospital of Butare Research and Ethics Committee. The approval to collect data from Kabyayi District Hospital was obtained through the Ministry of Health (Nº 20/3795/MIN/2019).

All research team members avoided discussing sensitive information concerning individuals where they may be overheard or leave individual's information, either on paper or on computer screens, where they can be seen by other patients/subjects, unauthorized health care staff, or the public. The PI ensured that all paper-based data collection tools are shredded and disposed of appropriately as soon as possible after the completion of the study. Data is accessible only by the research team and overseen by the Principal Investigators (PIs), who possess passwords and keys to enter. Only de-identified data untraceable to study participants were retained after study completion by the study investigators. Subsequently, only the named study investigators had access to the de-identified data. De-identified data may be shared with the health facility leadership and regulatory bodies as may be required for oversight.

Chapter III: DATA PRESENTATION AND ANALYSIS

A total of 330 adults with hypertension from three different hospitals were enrolled. We had 147, 100, and 83 participants from CHUK, Kabgayi District Hospital, and CHUB respectively. One patient died before follow-up. The remaining 329 patients were followed up for 6 months. At the end of the study, 21 patients had incomplete data for interpretation of their adherence, so they were excluded and the remaining 308 were analyzed (Figure 1).

Figure 1: Participants' recruitment flow chart

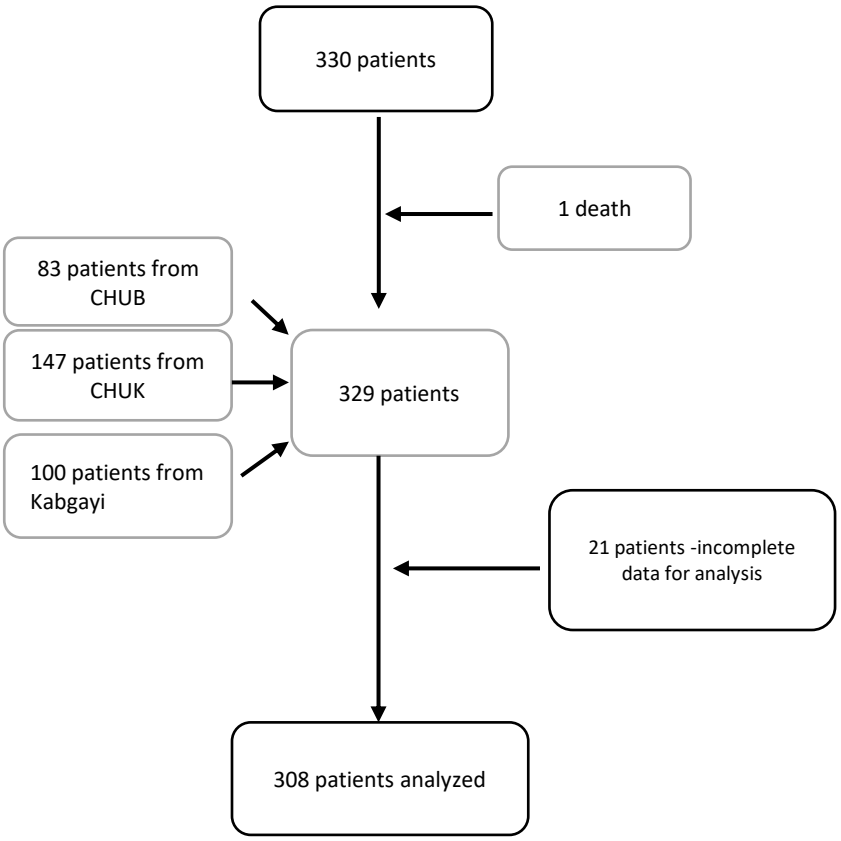


Table 1: Demographic characteristics of study participants

Variables	N (308)	%
Sex		
Female	243	78.9
Male	65	21.1
Age (Mean ± SD)	60 ± 12.8 years	
Age category		
18-39 years	17	5.5
40-59 years	118	38.3
≥60 years	173	56.2
Employment status		
Employed	58	18.8
Retired	23	7.5
Unemployed	227	73.7
Marital status		
Married	165	53.6
Widowed	108	35.1
Single	18	5.8
Divorced	14	4.5
Separated	3	1.0
Highest level of education		
None	72	23.4
Primary school	164	53.2
Secondary school	64	20.8
University degree	8	2.6
Economic category (Ubudehe)		
Category I	28	9.1
Category II	90	29.2
Category III	189	61.4
Category IV	1	0.3

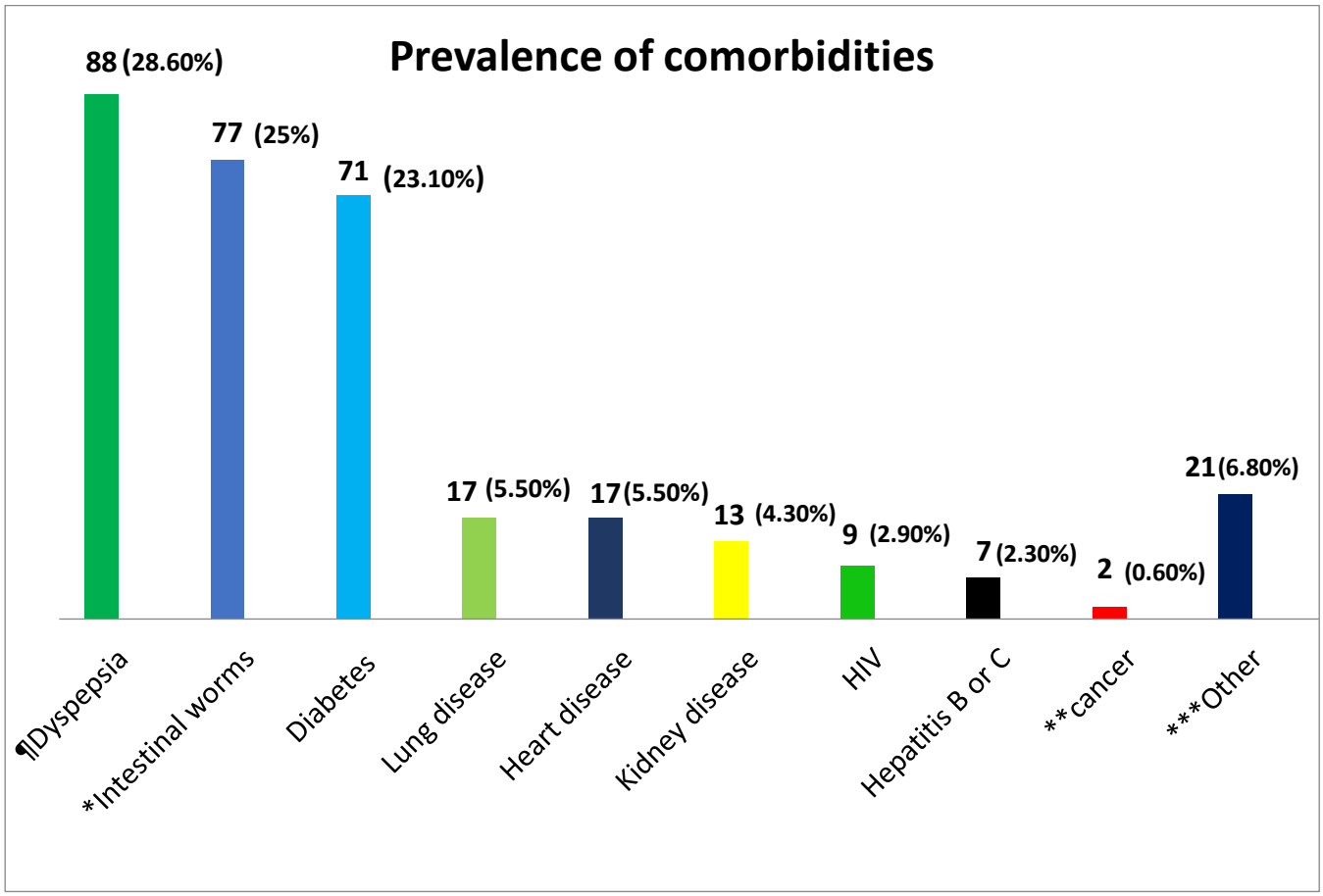
The sociodemographic characteristics of participants are summarized in *Table 1and Table 2*. The majority of participants (78.9%) were female. Most of the patients were greater than 60 years old with the mean ±SD age of 60 ± 12.8 years. The majority of participants were married, unemployed and their highest level of education was a primary school. More than half (61.4%) were in Ubudehe category III. A significant number of recruits (44.5%) were from CHUK which is not surprising because this hospital serves most of the Rwandan population.

Table 2: Social characteristics of study participants

Variables	n	%
Living conditions		
Alone	34	11.0
Spouse and children	115	37.3
Other family members	49	15.9
Children only	47	15.3
Spouse, children, and other family members	17	5.5
Spouse, children, and people not related to me	15	4.9
Spouse only	15	4.9
With parents only	3	1.0
Other	13	4.2
Travel time to see a doctor		
≤30min	100	32.5
30min-1hr	108	35.1
1hr-2hrs	71	23.1
≥ 2hrs	29	9.4
Transport means		
Bicycle	9	2.9
Foot	86	27.9
Moto	96	31.2
Bus	117	38.0
Requires a family member to go with		
Yes	81	26.3
No	227	73.7
Cigarette smoking/tobacco chewing		
Yes	13	4.2
No	295	95.8
Alcohol consumption		
Never	128	41.0
Stopped but I used to	133	43.2
Every day	5	1.6
Several times per week	4	1.3
Once a week to once a month	11	3.6
Once a month or less	27	8.8

Most of the participants were living with someone, although the majority did not require any family assistance to go to the hospital. The majority (35.1%) of patients take 30 minutes to an hour to reach the hospital and use the bus as a means of transport. Smoking was not common (4.2%) while 59% admitted having a history of alcohol intake with the minority being current drinkers.

Figure 2: Prevalence of comorbidities among study participants



**Intestinal worms: patients who had been diagnosed with intestinal worms*
***Cancer included prostatic cancer and gastric cancer.*
****Other: included non-chronic disease (Malaria, Tuberculosis, pneumonia, …)*
¶ Dyspepsia is defined as discomfort or pain in the upper abdomen with or without bloating, nausea, reflux, or belching.

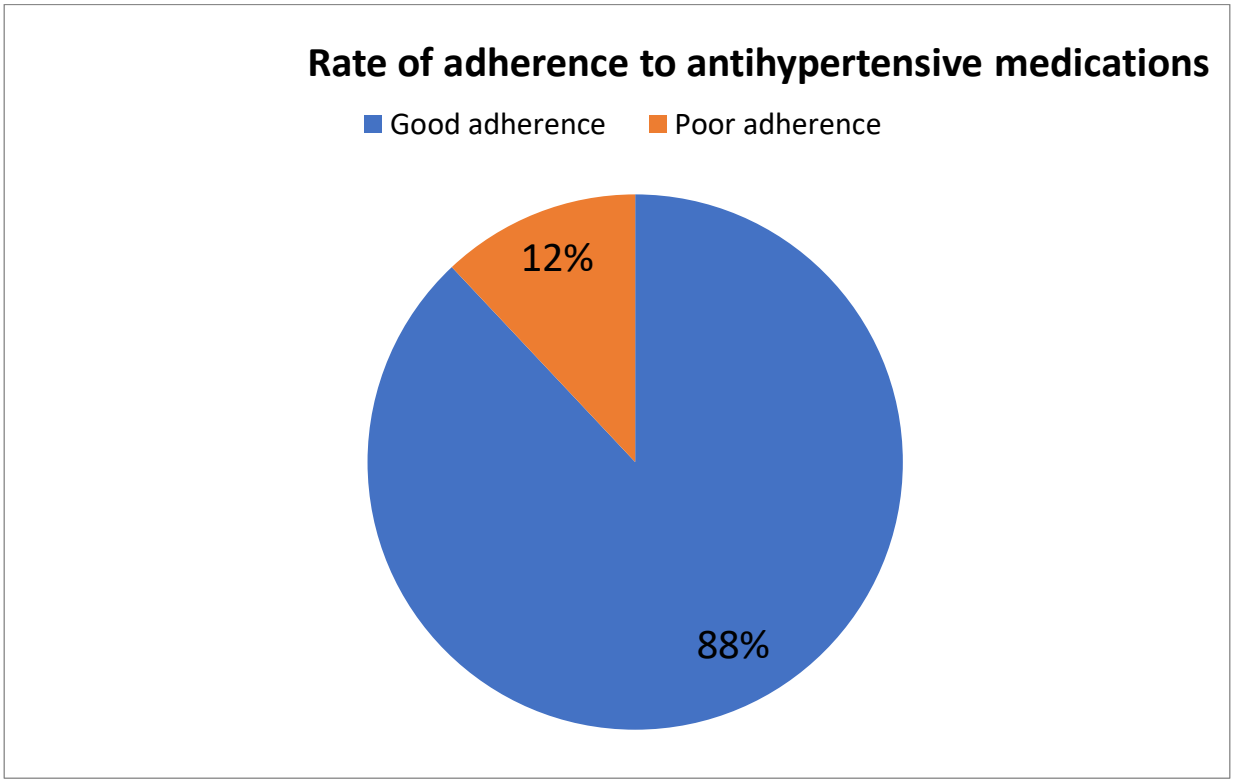
Dyspepsia was the most common co-morbidity at 28.6%, followed by intestinal worms (25.0%) and diabetes (23.1%). Heart disease and kidney diseases were present at 5.5 % and 4.3% respectively. Only 2.9% of participants were diagnosed with HIV infection and 2.3% of patients had either hepatitis B or C. The number of patients who reported hypertensive heart disease or cardiomyopathy as a result of their hypertension was 5.5%. Two participants (0.6%) reported a diagnosis of cancer.

Table 3: Social and clinical characteristics of study participants

Variables	N (308)	%
Taking Herbal remedies	13	4.2
Told by the doctor has high blood pressure	288	93.5
Had symptoms of blood pressure	265	86.0
Problems with affording medications	79	25.6
The seriousness of high blood pressure to the patient		
Not at all serious	47	15.3
Somewhat serious	109	35.4
Very serious	152	49.4
The satisfaction of medical care received at the clinic		
Very satisfied	237	76.9
Somewhat satisfied	66	21.4
Neither satisfied nor dissatisfied	1	0.3
Somewhat dissatisfied	2	0.6
Very dissatisfied	2	0.6
Frequency of missing blood pressure medications		
Nearly every day or every day	2	0.6
Several times per week	14	4.5
Once a week to once a month	11	3.6
Once a month or less	46	14.9
Never	235	76.3
Number of medications prescribed		
One medication	111	36.0
Two medications	165	53.6
Three or more medications	32	11.0

The majority of participants (93.5%) indicated they had been told by a doctor that they had hypertension, although only approximately half of them took this disease very seriously (49.4%). As many as 76.9% of participants were very satisfied with the care they receive at their clinics and more than half (53.6%) of recruits were taking two medications and only a few (0.6%) admitted to missing a dose every day.

Figure 3: Rate of adherence to antihypertensive medications among study participants



With good adherence defined as taking ≥ 80% of prescribed pills, we found 88% of the study participants to have a good adherence rate. The mean individual adherence rate was 91.5% with 95% CI = 89.7-93.3.

Table 4: Associations of adherence to antihypertensive medications

Predictors	Adherence		COR (95% CI)	p	AOR (95% CI)	p
	Good	Poor				
Sex						
Female	212 (87.2%)	31 (12.8%)	1.4 (0.5-3.6)	0.439	-	
Male	59 (90.8%)	6 (9.2%)				
Number of medications						
1 medication	104 (90.4%)	11 (9.6%)				
≥2 medications	167 (86.5%)	26 (13.5%)	1.5 (0.7-3.1)	0.309	-	
Age						
18-39 years	16 (94.1%)	1 (5.9%)	0.4 (0.05-3.2)	0.395	-	
40-59 years	105 (89.0%)	13 (11.0%)	0.8 (0.4-1.6)	0.563	-	
≥60 years	150 (86.7%)	23 (13.3%)	ref			
Smoking						
Yes	11 (84.6%)	2 (15.4%)	1.5 (0.3-6.3)	0.703	-	
No	260 (88.1%)	35 (11.9%)				
Education						
None	68 (94.4%)	4 (5.6%)	0.9 (0.2-4.1)	0.984	1.0	1.0
Primary school	136 (82.9%)	28 (17.1%)	3.4 (1.2-10.2)	**0.025**	3.0 (1.1-8.7)	**0.035**
Secondary& University	67 (93.0%)	5 (7.0%)	ref			
Alcohol consumption						
Yes	165 (91.6%)	15 (8.3%)	0.4 (0.2-0.8)	**0.021**	-	
Never	106 (82.8%)	22 (17.2%)				
Taking herbal remedies						
Yes	12 (92.3%)	1 (7.7%)	0.6 (0.07-4.7)	0.628	-	
No	259 (87.8%)	36 (12.2%)				
Medical care satisfaction						
Yes	267 (88.1%)	36 (11.9%)				
No	4 (80.0%)	1 (20.0%)	1.8 (0.2-17.0)	0.585	-	
Forget taking medications						
Never	219 (93.2%)	16 (6.8%)				
Yes	52 (71.3%)	21 (27.7%)	5.5 (2.7-11.3)	**<0.001**	5.2 (2.5-10.8)	<**0.001**
SEAMS scale score						
Good score	177 (86.8%)	27 (13.2%)				
Poor score	94 (90.4%)	10 (9.6%)	0.7 (0.3-1.5)	0.357	-	
BMQ scale scores						
Poor score	127 (83.0%)	26 (17.0%)	2.7 (1.3-5.6)	**0.009**	-	
Good score	144 (92.9%)	11 (7.1%)				

The most remarkable finding is that good adherence to antihypertensive medications was 88%. In this study, we found four statistically significant predictors of poor adherence. These were alcohol intake (p = 0.021, COR = 0.4, 95% CI: 0.2-0.8), forgetting to take medication (p <0.001, CI: COR = 5.2, 95% CI = 2.7-11.3) and having primary school level (p=0.025, COR=3.0, 95% CI=1.1-8.7). Having a poor score on the BMQ scale (p = 0.009, COR = 2.7, 95% CI = 1.3-5.6). Notably, we did not find any association with age or gender, smoking, number of medications, or medical care satisfaction, or good SEAMS score with poor adherence.

CHAPTER IV: DISCUSSION

This study aimed to determine the rate of adherence to antihypertensive medications in primary settings in Rwanda. 308 patients from 2 referral hospitals and one district hospital completed the study. The overall rate of good adherence was 88% with a good adherence rate defined as taking ≥ 80% of prescribed pills (21)(45). Major factors associated with poor adherence in our study were alcohol intake, forgetting to take medications and poor BMQ scores.

The adherence rate in our study was superior compared to a previous study done in Rwanda using MMAS-8 which found the adherence rate to be 77% (20). This study used MMAS-8, which is a self-report evaluation tool subject to reporting bias where there is a possibility of patients reporting greater adherence than the true level. We used a pill count methodology with unannounced home visits which likely has higher accuracy(27). The adherence rate was significantly better than that seen in a study done in 12 African countries using the 8-item Morisky Medication Adherence Score (MMAS-8) where only 35.6% of participants had high adherence to antihypertensive medication (46). We found a much lower level of non-adherence (12%) compared to what was found in a systematic review of 42 studies done in 19 developing countries (including 4 African countries) that used different assessment tools (mostly MMAS-8) with one study using pill count and another using BMQ, which found the mean rate of non-adherence to be 47.34% (35). Our results are close to what was found in a study done in Namibia using a modified Hill-Bone scale, which showed a mean adherence level of 76.7±8.1% (21).

In our study, we found that participants who admitted to drinking had an increased risk of being poorly adherent compared to a never drinker, with COR (95%CI): 0.4 (0.2-0.8) with a *p-value* of 0. 021. This can be explained by the fact that taking alcohol might increase the risk of forgetting your medications which also was found to have statistically significant associated with poor adherence. The other reason could be that these patients might use the money for alcoholic beverages instead of buying medications. Antihypertensive adherence studies performed in Ethiopia and India also found that alcohol intake was inversely associated with good adherence (47)(48).

A systematic review that examined the effect of alcohol consumption on adherence to medication in chronic disease showed negative effects of alcohol consumption on adherence, but the evidence was less consistent in non-HIV studies (49). A population-based study estimating the national prevalence of hypertension in Rwanda found that a history of smoking or alcohol was associated with a higher prevalence of hypertension (10). Surprisingly our study did not find a big number of participants who smoke (4.2%) but at least 58.5% of participants had a positive history of alcohol intake.

The second association of poor adherence in our study was the fact of forgetting to take medications with COR (95%CI) 5.5 (2.7-11.3), with a $p<0.001$. This variable remained statistically significant even after adjusting for multivariate analysis with medication ($p <0.001$, CI: COR = 5.2, 95% CI = 2.5-10.8). One study was done in Gondar Comprehensive Specialized Hospital, Ethiopia showed "forgetfulness" as one of the most commonly mentioned reasons for poor adherence and was reported in 20.1% of patients(50). In another study assessing factors affecting compliance to antihypertensive medications in tertial hospitals in Mumbai found "forgetfulness" as one of the prevalent reasons for noncompliance in 41.2% of participants (51). Forgetfulness was cited as one of the factors associated with non-adherence in hypertensive elderly Chinese Americans (52).

This study found participants with the highest level of education of primary school were likely to be less adherent compared to patients with no level of educations (COR (95%)3.4 (1.2-10.2) with a *p-value* of 0.025 which remained significant after adjusting for multivariate analysis (p=0.035, AOR (95%) 3.0 (1.1-8.7). This could be explained by the fact people with no education tend to have faith in physicians and are likely to follow the given recommendations and highly educated participants tend to be skeptical toward antihypertensive medications. A study done in Ghana and Nigeria using MMAS-8 to assess factors associated with non-adherence found participants with any form of formal education were more likely to be non-adherent (53).

We found a strong statistical significance between good BMQ score and good adherence COR (95% CI) 2.7 (1.3-5.6) with a *p-value* of 0.009. This reminds us of the importance of explaining hypertension and discussing the patients' concerns and beliefs about medications needs to be stressed. These findings are consistent with what was found in a systematic review looking at factors associated with adherence to cardiovascular medications in a resource-limited setting where negative perceptions about medications were statistically associated with poor adherence (26).

In another study evaluating adherence to long-term therapies and beliefs about medication, with more than half of the subjects having hypertension, low adherence among patients on long-term medications was high and was related to negative beliefs about medications (54). We did not find a statistically significant correlation between SEAMS score and level of adherence COR (95%CI) 0.7 (0.3-1.5) with p=0.357.

The majority of participants (78.8%) were female and were middle-aged with a mean age (mean ±SD) of 60±12.8 years. Although a big number of our study population was unemployed (73.7%), a majority of them were in the UBUDEHE category 3 (61%) which in the middle class and this could mean that a majority of them can afford medications.

Although smoking, taking more than two medications and use of herbal remedies were found in other studies to be associated with poor adherence (47)(35)(48), we did not find an association for these variables. This can be partially be explained by the fact that in our study the percentage of participants who were smoking or using herbal remedies were both 4.2%, yet we suspect the rate to be higher as patients may not want to reveal the truth about taking herbal medications.

Gender was not associated with adherence rate in our study (OR (95%CI) 1.4 (0.5-3.6) with a *p-value* of 0.439). Patient medical care satisfaction was not found to be a statistically significant variable in our study (OR (95%CI) 1.8 (0.29-10.8) with *p*=0.525) contrary to a study done in Nigeria which found a strong positive correlation between medication adherence and patient satisfaction, and another study performed in Palestine evaluating the relationship between treatment satisfaction and medication adherence (55)(56).

We highlight some of the strengths of the study. To our current knowledge, this is the first study done in Rwanda that assessed the rate of adherence to antihypertensive medications. It has enrolled a good number of participants from different sites including major referral hospitals in Rwanda and one district hospital to establish variation in the study population. The rate of loss to follow-up was 6%. Although not ideal, we believe it does not cause a serious threat to the validity of the results.

The limitations of this study are also worth mentioning. The home visit is intrusive and raises the questions of the potential Hawthorne effect. Although the pill count method is accurate and objective, measures adherence over weeks, and limit pills dumping, it does not accurately pick up some adherence patterns like drug interruptions which can impact outcomes. Another limitation of this study resides in pill count methodology which as all self-reported methods depending largely on patients' memory, is subject to recall bias. Other studies using more accurate methods like pillbox are needed.

CHAPTER V: CONCLUSIONS AND RECOMMENDATIONS

5.1. CONCLUSION

This was a prospective, cohort study on adherence to antihypertensive medication in primary settings in Rwanda using unannounced home visit pill count and survey methodology. The evidence from this study suggests the majority of participants have good adherence. Having primary school as a high level of education, alcohol intake, forgetting to take medications and negative beliefs about medications were strongly associated with poor adherence. Only the primary education level and forgetting to take medications remained statistically significant after multivariate analysis. Other predictions including taking more than two medications, smoking, herbal remedies were not statistically significant although we still believe they are clinically significant.

5.2. RECOMMENDATIONS

Adherence in our settings was good, but this should not be the reason to loosen efforts everyone should put in patients' education. To the Ministry of Health/Rwanda Biomedical Center, we recommend raising awareness to the patients with hypertension for them to remember to take the medication. Availing posters to the Health centers and NCD clinic, massive media discussion on radio or television would be one way to accomplish this.

Beliefs and concerns about medicine need to be addressed during patient health education to optimize adherence and, thereby, medication effectiveness. The nurses and physicians, especially those working in NCD clinics, should devote their time to optimize communication between physicians and patients. Irrespective of their education status, patients need health education about hypertension (being asymptomatic may make it difficult to take medication when there is no symptomatic relief) and the side effects of medications.

Although smoking was not statistically significant as a predictor of adherence, smoking cessation as a modifiable cardiovascular risk as well as alcohol intake reduction should be included in patients' health education during follow up visits as part of behavioral modification as part of hypertension management.

Finally, the Rwandan population is aging and living longer. We can expect the number of patients with hypertension to increase. More is required from health workers, hospitals, and health insurance groups to understand the problem of hypertension and its complications among the Rwandan population and to avail of antihypertensive medications.

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ANNEXES

Data collection form-English version

For official use only
Survey location:

_____
Contacts:

Date: ___/___/____
Survey ID: _____

Hypertension (high blood pressure) adherence questionnaire

Thank you for participating in this questionnaire to understand why some people may have difficulty taking their blood pressure medications. As stated in the informed consent form, your answers to these questions will be kept confidential and your name will not be used or recorded in our study at any time.

This survey will take approximately 10 minutes of your time. Thank you kindly for your time.

Please check (✔) or mark with an X the box beside your answer.

Part I

1. What is your gender?
   ☐ Male ☐ Female

2. Please write your age in years in the space below.

   _____

3. What is your employment status? (If you are a farmer, please mark employed)
   ☐ employed ☐ unemployed
   ☐ retired

4. What is your marital status?
   ☐ single ☐ married ☐ widowed
   ☐ divorced ☐ separated

5. What is the highest level of education you have completed?
   ☐ primary school ☐ junior secondary school
   ☐ senior secondary school ☐ university bachelor's degree
   ☐ university advanced degree ☐ none

6. Which of the following **one best describes** who you live with at home? I live...
   - ☐ alone
   - ☐ with spouse only
   - ☐ with spouse and children
   - ☐ with a spouse, children, and people not related to me
   - ☐ with a spouse, children, and other family members
   - ☐ with other family members
   - ☐ other

7. Which UBUDEHE category do you belong to?
   - ☐ category 1
   - ☐ category 2
   - ☐ category 3
   - ☐ category 4

8. How long does it take you to get to see the doctor or other person who prescribes your medications?
   - ☐ l≤30min
   - ☐ 30min-1hr
   - ☐ 1hr-2hrs
   - ☐ ≥ 2hrs

9. What kind of transport means do you use most often to get to the doctor? If more than one, please pick the one that transport method that you spend the most time on.
   - ☐ foot
   - ☐ bicycle
   - ☐ moto
   - ☐ bus

10. Do you **require** a family member or friend to come with you to the clinic?
    - ☐ yes
    - ☐ no

11. Do you smoke cigarettes or chew tobacco?
    - ☐ yes
    - ☐ no

12. How often do you drink alcoholic beverages, such as banana beer, beer, wine, or liquor?
    - ☐ never
    - ☐ once a month or less
    - ☐ once a week to once a month
    - ☐ several times per week
    - ☐ nearly every day or every day
    - ☐ I used to drink alcohol, but I no longer drink alcohol

13. Do you use any recreational drugs, such as marijuana, cocaine, or heroin?
    - ☐ yes
    - ☐ no

14. Please put a checkmark beside each medical illness that you currently have.
    - ☐ diabetes
    - ☐ heart disease
    - ☐ kidney disease
    - ☐ lung disease
    - ☐ cancer
    - ☐ hepatitis B or C
    - ☐ HIV/AIDS
    - ☐ syphilis
    - ☐ malaria
    - ☐ gastritis.
    - ☐ worms

15. Do you use any herbal remedies for your illnesses, such as herbal teas,…?
    - ☐ yes
    - ☐ no

16. Has your doctor or other health care provider told you that you have high blood pressure?
    - ☐ yes
    - ☐ no

17. How serious of disease is high blood pressure to you?

☐ not at all serious
☐ somewhat serious
☐ very serious

18. Have you had any symptoms from your high blood pressure?
☐ yes ☐ no

19. Have you had or do you currently have problems affording your medication for high blood pressure?
☐ yes ☐ no

20. How satisfied are you with the care you receive at the clinic?
☐ very dissatisfied
☐ somewhat dissatisfied
☐ neither satisfied nor dissatisfied
☐ somewhat satisfied
☐ very satisfied

21. About how often do you miss doses of your blood pressure medication(s)? Even if you miss the medication because you cannot obtain it or afford it, please mark the one that best describes how often you miss a dose.
☐ never
☐ once a month or less
☐ once a week to once a month
☐ several times per week
☐ nearly every day or every day

22. How many medications (that your doctor has prescribed) do you take every day?
☐ one.
☐ two
☐ three
☐ four
☐ five
☐ six or more

Part II

Below, you will find a series of questions. You should mark the box beside each question that describes your level of confidence for each question.

How confident are you that you can take your medicines correctly…?

1. How confident are you that you can take your medicines correctly when you take several different medicines each day?
☐ not confident ☐ somewhat confident ☐ very confident

2. How confident are you that you can take your medicines correctly when you have a busy day planned?
☐ not confident ☐ somewhat confident ☐ very confident

3. How confident are you that you can take your medicines correctly when you are away from home?
☐ not confident ☐ somewhat confident ☐ very confident

4. How confident are you that you can take your medicines correctly when no one reminds you to take the medicine?
☐ not confident ☐ somewhat confident ☐ very confident

5. How confident are you that you can take your medicines correctly when you take medicines more than once a day?
☐ not confident ☐ somewhat confident ☐ very confident

6. How confident are you that you can take your medicines correctly when the schedule to take the medicine is not convenient?
☐ not confident ☐ somewhat confident ☐ very confident

7. How confident are you that you can take your medicines correctly when your normal routine gets messed up?
☐ not confident ☐ somewhat confident ☐ very confident

8. How confident are you that you can take your medicines correctly when you get a refill of your old medicines and some of the pills look different than usual?
☐ not confident ☐ somewhat confident ☐ very confident

9. How confident are you that you can take your medicines correctly when you are not sure how to take the medicine?
☐ not confident ☐ somewhat confident ☐ very confident

10. How confident are you that you can take your medicines correctly when you are not sure what time of the day to take your medicine?
☐ not confident ☐ somewhat confident ☐ very confident

11. How confident are you that you can take your medicines correctly when a doctor changes your medicines?
☐ not confident ☐ somewhat confident ☐ very confident

12. How confident are you that you can take your medicines correctly when they cause some side effects?
☐ not confident ☐ somewhat confident ☐ very confident

13. How confident are you that you can take your medicines correctly when you are feeling sick (like having a cold or the flu)?
☐ not confident ☐ somewhat confident ☐ very confident

Part III

Below you will find a series of statements. Please mark the box that indicates how much you agree or disagree with the statement.

1. My health, at present, depends on my medicines
☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

2. My life would be impossible without my medicine
☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

3. Without my medicines, I would become very ill
☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree

☐ strongly agree

4. My health in the future will depend on my medicines

☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

5. My medicines protect me from becoming worse

☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

6. Having to take medicines worries me

☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

7. I sometimes worry about the long-term effects of my medicines

☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

8. My medicines are a mystery to me

☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

9. My medicines disrupt my life

☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

10. I sometimes worry about becoming too dependent on my medicines

☐ strongly disagree
☐ disagree
☐ neither agree nor disagree
☐ agree
☐ strongly agree

The survey is now complete. Thank you for your participation in this survey. We appreciate your time.

Data collection form- Kinyarwanda version

Huzuzwa n'umushakashatsi

Survey location (Ahabera ikusanyamakuru):
_____
Date (Italiki): ___/___/____
Survey ID (Numero y'ikusanyamakuru):
_____
Antihypertensive medication(s)
(Imiti y'umuvuduko w'amaraso uri hejuru ufata):
_____
Frequency (inshuro ufata imiti kumunsi):
_____
Quantity prescribed (ingano y'imiti yandikiwe):
_____
Date prescribed (itariki yandikiweho imiti) :
_____

Ibibazo bimenyekanisha ubwitange bw'iminywere y'imiti y'umuvuduko w'amaraso uri hejuru.

Murakoze kwitangira gusubiza ibi bibazo bitumenyesha uko abantu bamwe bibagora gufata imiti y'umuvuduko w'amaraso. Nkuko byavuzwe muri consent form, ibisubizo byanyu bizagirwa ibanga kandi izina ryanyu ntirizamenyekanishwa cyangwa ngo rikoreshwe muri ubu bushakashatsi n'igihe na kimwe.

Ibi bibazo birabatwara iminota itarenze 10. Murakoze kubw'igihe cyanyu.

Andika (✔) or cyangwa X mugasanduku kegereye igisubizo cyanyu.

Igice cya I

1. **Igitsina..?**

□Gabo □Gore

2. Ufite imyaka ingahe?

3. Urakora cyangwa ntukora?

□ ndakora

□ sinkora

□ ndi mu kiruhuko cy'izabu

4. Uri ingaragu cyangwa urubatse?

□ ndi ingaragu

□ ndubatse

□ twatandukanijwe namategeko

□ narapfakaye

□ twaratandukanye

5. Wagejeje he mu ishuli?

□ sinize

□ primaire □ secondaire (3 abanza)

□ secondaire (3 ya nyuma) □ kaminuza (ikiciro cya mbere)

□ kaminuza (ikiciro cya kabiri)

6. Muri ibi bikurikira, ni ikihe kivuga neza uwo mubana?

□ Mba**...** jyenyine

□ Nuwo twashakanye gusa

□ n'uwo twashakanye n'abana

□ n'umufasha, abana, n'abantu tudafitanye isano

□ n'umufasha, abana, n'abo mu muryango

□ n'abo mu muryango

□ abandi

□ Abana

☐ N’ababyeyi

7. Uba mu cyiciro cya kangahe cy’ubudehe?

☐ icya mbere

☐ icya kabiri

☐ icya gatatu

☐ icya kane

8. Ugenda urugendo rungana iki kugira ngo ubonane na muganga cyangwa se undi ukwandikira imiti?

☐ munsi y’iminota 30

☐ hagati ya 30 -– isaha 1

☐ isaha 1 - amasaha 2

☐ hejuru y'amasaha 2

9. Ukoresha iki mu kuza kwa muganga, niba birenze uburyo bumwe hitamo ubwo ukunda gukoresha

☐ amaguru

☐ igare

☐ moto

☐ imodoka

10. Harubwo ukenera umuntu wo mu muryango cyangwa se inshuti kuguherekeza kwa muganga?

☐yego ☐oya

11. Harubwo unywa itabi cyangwa ngo urye ubugoro?

☐yego ☐oya

12. Ni kangahe unywa inzoga? Nk’urwagwa, byeri ,divayi, cyangwa rikeri

☐ntanarimwe

☐ rimwe mu kwezi cyangwa gake

☐ rimwe mu cyumweru kugeza kuri rimwe mu kwezi

☐ inshuro nkeya mu cyumweru

☐ hafi ya buri munsi cyangwa buri munsi

☐ nijyeze kunnywa ndabireka

13. Ukoresha ibiyobyabwenge, nka marijuwana, cocayine, cyangwa heroyine?

☐yego ☐oya

14. Emeza iruhande ya buri ndwara yose urwaye.

☐Diyabeti

☐umutima

☐impyiko

☐ibihaha

☐canseri

☐mararіya

☐umwijima B cyangwa C

☐igifu

☐Inzoka

☐SIDA

☐ STI

☐ ntazindi ndwara

☐ izindi

15. Ukoresha imiti ya Kinyarwanda kuburwayi bwawe?

☐yego ☐oya

16. Harubwo muganga wawe cyangwa undi muvuzi bakubwiye ko urwaye umuvuduko w'amaraso uri hejuru?

☐yego ☐oya

17. Wumva kugira umuvuduko w'amaraso uri hejuru ubiha ubukare bungana iki?

☐nta nagato

☐hagati na hagati

☐birakaze cyane

18. Hari ibimenyetso wagize byerekana indwara yawe y'umuvuduko w'amaraso uri hejuru?

☐yego ☐oya

19. Hari ikibazo ufite cyangwa wijyeze kugira cyerekeye kwishyura imiti y'umuvuduko w'amaraso?

☐yego ☐oya

20. Washimishijwe bingana gute nubufasha wahawe kwa muganga?

☐sinishimye

☐ninkaho ntishimye

☐sinishimye cyangwa ngo nishime

☐narishimye bigereranije

☐narishimye cyane

21. Ni nka kangahe usiba gufata imiti y'umuvuduko w'amaraso?nubwo wabura imiti -

☐ nta narimwe

☐ rimwe mu kwezi cyangwa gake

☐ rimwe mu cyumweru kugeza kuri rimwe mukwezi

☐ inshuro nkeya mu cyumweru

☐ hafi ya buri munsi cyangwa buri munsi

22. Ni imiti ingahe muganga yakwandikiye unywa buri munsi?

☐ umwe ☐ ibiri

☐ itatu ☐ ine

☐ itanu ☐ itandatu cyangwa hejuru yayo

Igice cya II

Munsi urabona urukurikirane rw'ibibazo. Emeza mu gasanduka kerekana neza uko wumva buri kibazo.

Wiyizeye bingana gute mu gufata neza imiti yawe….?

1. Wiyizeye bingana gute mu gufata neza imiti yawe igihe ufata imiti myinshi buri munsi?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

2. Wiyizeye bingana gute mu gufata neza imiti yawe iyo wagize umunsi ufitemo gahunda nyinshi?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

3. Wiyizeye bingana gute mu gufata neza imiti yawe iyo uri kure yo mu rugo?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

4. Wiyizeye bingana gute mu gufata neza imiti yawe iyo ntawukwibutsa gufata imiti?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

5. Wiyizeye bingana gute mu gufata neza imiti yawe iyo ufata imiti inshuro irenze imwe ku munsi?

☐Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

6. Wiyizeye bingana gute mu gufata neza imiti yawe iyo gahunda yo gufata iminti ikugoye?

☐Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

7. Wiyizeye bingana gute mu gufata neza imiti yawe iyo uko ukora buri munsi byivanze?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

8. Wiyizeye bingana gute mu gufata neza imiti yawe iyo ubonye imiti imwe y’ibinini bidasa n’ibyo wari usangannywe?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

9. Wiyizeye bingana gute mu gufata neza imiti yawe iyo utizeye neza uko ufata imiti?

☐Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

10. Wiyizeye bingana gute mu gufata neza imiti yawe iyo utazi neza amasaha yo gufata imiti?

☐Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

11. Wiyizeye bingana gute mu gufata neza imiti yawe iyo umuganga ahinduye imiti?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

12. Wiyizeye bingana gute mu gufata neza imiti yawe iyo wagize ibibazo bitewe n'imiti?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

13. Wiyizeye bingana gute mu gufata neza imiti yawe iyo wumva urwaye nk'ibicurane?

☐ Siniyizeye ☐ Ndiyizeye gake ☐ Ndiyizeye cyane

Igice cya III

Munsi urabona urukurikirane rw' ingingo. Emeza mu gasanduka kerekana neza uko wumva buri ngingo.

1. Ubuzima bwanjye, kur' ubu, bugizwe n'imiti

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

2.Sinabaho ntafite imiti

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

3.Narwara cyane nta miti mfite

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

4.Ubuzima bwanjye bw'ahazaza buzagirwa n'imiti

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

5.Imiti yanjye indinda kuba naremba

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

6. Gufata imiti birampangayikisha

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

7. Hariho igihe ingaruka z'imiti mfata zimpangayikisha

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

8. Imiti yanjye sinyiyumvisha neza

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

9.Imiti impungabanyiriza
ubuzima

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

10. Hariho igihe mpangayikishwa no kuba nagengwa cyane n'imiti

☐ Simbyemeye na gato

☐ Simbyemeye

☐ Sinemeye cyangwa ngo nemere

☐ Ndemeye

☐ Ndemeye cyane

Iri kusanyamakuru rigeze kumusozo. Murakoze kuba mwafashe umwanya wanyu gusubiza ibibazo. Turabishimiye.

House visit pill count

Adherence to antihypertensive medications in the primary care setting in Rwanda
Survey ID: _____

Please complete the parts in yellow

Your surname: _____

Your phone number:_____

Your address / where do you live?
_____

_____

Date house visit performed: _____

Antihypertensive medication(s): _____

Frequency: _____

Quantity prescribed: _____

Date prescribed: _____

Date started taking this medication: _____

Number of pills the patient should have taken at this point: _____

Number of pills the patient has taken at this point: _____
Additional notes:

Consent form -English version

Informed Consent Form for Adherence to antihypertensive medications in primary settings in Rwanda

This Informed Consent Form is for adult men and women who we are inviting to participate in research on how often you take your medication for your blood pressure and what difficulties you have in taking your blood pressure medication. The title of our research project is "Adherence to antihypertensive medications in primary settings in Rwanda."

This Informed Consent Form has two parts:
• Information Sheet (to share information about the research with you)
• Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

PART I: Information Sheet

Introduction

My name is Dr. NIYOMWUNGERI Reverien, Resident in Internal Medicine in the University of Rwanda College of Medicine and Health Sciences (UR/CMHS). We are performing a research on any difficulties you have in taking your blood pressure medications. We would like to understand these difficulties so that we can help people to take medications for this common disease.

I am going to give you information and invite you to participate in this research. You do not have to decide today if you would like to participate in this research. If you do not understand some of the words or concepts, please let me know and I will take the time to explain it to you. Before you decide on whether you would like to participate in this research, you can discuss it with anyone you feel comfortable with who could help you. If you have any questions at any time, you can discuss it with me or with any staff involved in the study.

Purpose of the research

High blood pressure (hypertension) is very common in Rwanda. If untreated, the disease can result in strokes, heart attacks, kidney problems, and many more. We would like to know how often

people are taking their blood pressure medications, and if they are not taking them very often we would like to understand why so that we can help people to take their medications.

Type of Research Intervention

This research will have you complete a survey on information's about your pills. You will also be asked to sign a consent on surprise home visits, where we will visit you at your home to assess how you are taking medications. You will also be asked to bring the left-over of your medications when you present to your next rendez-vous

Participant selection

We are inviting all adults who attend this and other clinics who have high blood pressure to participate in this study.

Voluntary Participation

Your participation in this research is entirely voluntary. You can decide whether to participate or not. If you choose not to participate you will continue to receive all the same services that you had previously received at this clinic and nothing will change. You can choose to stop participating in this study any time that you like and your prior service will continue as before.

Information on the survey.

If you choose to participate in this survey, you will complete a brief survey form that should take 10 minutes. This survey will help us understand how often you take your blood pressure medication and if you miss some doses of your medication, it will help us understand why you miss doses.

.

Procedures and Protocol

There are two parts of this study if you choose to participate. In the first part, you will be asked to fill out a brief (10 minute) questionnaire. The answers to your questions will be stored in a file that is locked on a computer that is locked, and your name will not be used anywhere in this file.

In the second part of the study, we will visit you at home, unannounced, we will calculate the number of pills you have taken and the remainder will be recorded.

Duration

This research will take place over a total period of 9 months, during which you will be requested to come to the clinic for a follow-up visit one month after today (or one month after the day you decide to start participating in this study). On the first day you participate, it will take a total of 20 minutes of your time, and on the follow-up appointment at the clinic, you will spend approximately 5-10 minutes involved in this study.

Side Effects

There are no side effects associated with participating in this study.

Risks
There are no anticipated risks with participating in this study.

Reimbursements
There is no reimbursement for your participation in this study.

Confidentiality
The information that we collect from this study will be confidential. We will not be sharing the identity of those participating in the research. Information that we collect about you will be stored in a locked file on a locked computer. Any information about you in this file will have a number on it instead of your name. Only the researchers will know this number and we will keep it locked. This file will not be shared with anyone except for those directly involved in the study.

Sharing the results
We plan to publish the results of the study in journals. Your confidentiality will not be breached at any time.

Right to Refuse or Withdraw
You have no obligation to take part in this research and if you choose to not participate, there will be no penalty or change in your care at this clinic. You can also stop participating in this study at any time that you like and your care at this clinic will not be impacted.

Who to Contact
You can ask questions at any time during this study. You can ask them now, or if you would like to ask questions in the future, you may contact: Dr. NIYOMWUNGERI Reverien, niyorever@gmail.com or Dr. Dennis Hopkinson at dahopk@gmail.com.

Part II: Certificate of consent

I have read the information regarding this study as above, or this information has been read to me. I have been able to ask all questions that I have and these have been answered to my satisfaction. I consent to voluntarily be a participant in this study.

Printed Name of Participant_____

Signature of Participant _____

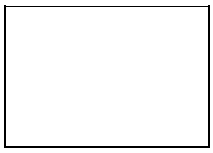
Date _____
Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____

AND Thumbprint of participant:



Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent:
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the above information.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

Consent form Kinyarwanda version (Translated)

Inyandiko yemerera kwinjira mu bushakashatsi ku bwitange bwo kunywa neza imiti y'umuvuduko w'amaraso uri hejuru mu Rwanda.

Iyi nyandiko iteganirijwe abagabo n'abagore bategerejwe kwinjira mu bushakashatsi bwerekana uko bafata imiti y'umuvuduko w'amaraso uri hejuru n'inzitizi bahura nazo mu gufata imiti yabo. Umutwe w'ubushakashatsi witwa "ubwitange bw'iminywere y'imiti y'umuvuduko w'amaraso uri hejuru mu Rwanda"

Iyi nyandiko ifite ibice bibiri:
- Igice cyo kumenyesha amakuru ku bushakashatsi
- Icyemezo cy'uruhushya (imikono by'abemeye kwinjira mu bushakashatsi)

Wemerewe fotokoti y'iyi nyandiko.

IGICE I: Icyiciro cy'amakuru.

Intangiriro

Nitwa muganga Reverien NIYOMWUNGERI, ndi umunyeshuli muri Kaminuza y'u Rwanda ndi kwiga kuba inzobere mu gashami kavura indwara zo mu mubiri. Turi gukora ubushakashatsi ku bibazo ushobora guhura nabyo mu gufata imiti y'umuvuduko w'amaraso. Twifuzaga kumva neza izo nzitizi kugira ngo dushobore gufasha abantu bafite indwara y'umuvuduko w'amaraso.

Ndabamenyesha kandi mbatumira mu kwinjira muri ubu bushakashatsi. Ntutegetswe gufata icyemezo cyo kwinjira mu bushakashatsi uyu munsi. Niba hari amagambo cyangwa se ibindi utumva, nibyiza ko wambwira nkafata umwanya nkagusobanurira. Mbere y'uko ufata umwanzuro wo kwinjira muri ubu bushakashatsi, ushobora kubiganiraho n'umuntu wumva wisanzuyeho ushobora kugufasha. Igihe cyose wumva ufite ikibazo, wasanga jyewe cyangwa se undi muntu uri gukora ubu bushakashatsi.

Intego y'ubu bushakashatsi

Umuvuduko w'amaraso uri hejuru ni indwara yibasiye benshi mu Rwanda. Itavuwe, ishobora gutera indwara nka paralizi ,indwara y'umutima, ibibazo by'impyiko, n'ibindi byinshi. Icyo dushaka ni ukumenya inshuro abafite iki kibazo bafata imiti bahawe, kandi niba batayifata bihagije turashaka kumva neza impamvu ibitera kugirango tubafashe muri icyo kibazo.

Ibizakorwa muri ubu bushakashatsi

Ubu bushakashatsi buzagusaba kuzuza ikusanyamakuru, bitewe n'uburenganzira bwawe tugusure murugo tubare ibinini usigaranye ku miti y'umuvuduko w'amaraso uri hejuru.

Gucagura abinjira mu bushakashatsi

Dutumiye abakuze bose bivuriza kuri iri vuriro ndetse n'ayandi mavuriro bafite umuvuduko w'amaraso uri hejuru kwinjira muri ubu bushakashatsi.

Amahitamo ya buri wese (amahitamo y'uruhare rwawe)

Kugira uruhare muri ubu bushakashatsi ni ubushake bwa buri wese. Ushobora guhitamo kugiramo uruhare cyangwa ukabyanga. Nuhitamo kutagira uruhare uzakomeza guhabwa ubufasha warusanzwe ubona; ntakizahinduka. Ushobora no guhitamo guhagarika kwinjira muri ubu bushakashatsi igihe cyose wifuza ubufasha wahabwaga bugakomeza.

Amakuru ku ikusanyamakuru no kubara ibinini

Nuhitamo kwinjira muri ubu bushakashatsi, uzuzuza ikusanyamakuru itazafata iminota irenze 10. Iri kusanyamakuru rizadufasha kumenya inshuro ufata imiti y'umuvuduko w'amaraso uri hejuru kandi niba ujya usiba kuyifata, bizadufasha kumenya impamvu.

Nuhitamo kujya mubushakashatsi tuzagusura murugo tugutunguye kugira ngo tubare ibinini usigaje by'umuvuduko w'amaraso uri hejuru.

Uko bizakorwa

Hari ibice bibiri muri ubu bushakashatsi nuhitamo kubigiramo uruhare. Mu gice cya mbere, uzasabwa gusubiza ibibazo bizagufata iminota 10. Ibisubizo byawe bizabikwa kuri mudasobwa ifite umubare w'ibanga usabwa kuyifungura kandi amazina yawe ntabwo azakoreshwa.

Mugice cya kabiri muri ubu bushakashatsi, tuzagusura murugo iwawe kugira ngo tubare ibinini. Tuzandika umubare w'ibinini usigaje niturangiza twigendere.

Igihe ubushakashatsi buzamara

Ubu bushakashatsi buzafata amezi ageze ku 9, ku nshuro yambere uzinjira mu bushakashatsi bizafata nk'iminota 20 noneho nituza iwawe kugusura bifate hagati y'iminota 5 cyangwa 10.

Ingaruka

Nta ngaruka zihari zigendanye no kugira uruhare muri ubu bushakashatsi.

Ibyago

Nta byago biteganywa bigendanye no kujya muri ubu bushakashatsi.

Kwishyurwa

Nta mafaranga uzahabwa mu kwinjira muri ubu bushakashatsi.

Kugirirwa ibanga

Ubumenyi dukusanya muri ubu bushakashatsi buzagirwa ibanga. Amakuru tuzakusanya muri iyi nyigo azagirwa ibanga. Ntituzijyera tugaragaza umwirondoro w'abinjiye muri ubu bushakashatsi. Amakuru tuzakuzanya muri ubu bushakashatsi azabikwa muri mudasobwa ifunze. Amakuru kuri wowe azahabwa umubare kugira ngo amazina yawe atagira aho agaragara kuri iyi nyandiko.
Abashakashatsi bonyine nibo bazamenya uyu mubare. Aya makuru ntazigera asangizwa uwariwe wese kereka uri muri ubu bushakashatsi.

Gutangaza ibyavuye mu bushakashatsi.

Turateganya gutangaza ibyavuye muri ubu bushakashatsi mu binyamakuru. Ibanga ryawe ntirizigera rizimurwa na rimwe.

Uburenganzira mu kuva mu bushakashatsi.

Ntabwo utegetswe kwinjira muri ubu bushakashatsi, nuhitamo kutabugiramo uruhari nta bihano uzahabwa cyangwa ngo uko witabwaho bihinduke. Ushobora guhagarika ubu bushakashatsi igihe icyo ari cyose kandi nta ngaruka bizagira ku buryo witabwagaho ku ivuriro.

Ukeneye andi makuru

Ushobora kubaza ibibazo igihe cyose uri muri ubu bushakashatsi. Ushobora kubibaza ubu , cyangwa niba wifuza kuzabibaza nyuma wabaza muganga NIYOMWUNGERI Reverien, niyorever@gmail.com / 0783567285 cyangwa muganga Dennis Hopkinson kuri dahopk@gmail.com.

Igice II: Icyemezo cyo kwinjira mu bushakashatsi ku bushake.

Nasomye neza kandi namenyeshejwe ibigendanye n'ubu bushakashatsi, cyangwa hari uwabinsomeye. Nabajije aho nari mfite urujijo kandi nasubijwe kuburyo buhahije. Nemeye ntagahato kwinjira muri ubu bushakashatsi.

Izina ry'ufata uruhare mu bushakashatsi_____

Umukono _____

Itariki _____

Umunsi/ukwezi/umwaka

Utabasha gusoma no kwandika

Nasomeye nta rujijo uwinjira mu bushakashatsi , yagize n'umwanya wo kubaza ibibazo.
Ndemeza ko yemeye kwinjira mu bushakashatsi nta gahato.

Izina ry'indeberezi _____
Igikumwe cy'uwinjira mu bushakashatsi:

Umukono w'indeberezi _____

Italiki _____

umunsi/ukwezi/umwaka

Ukwemera ku ukora ubushakashatsi/uwemera kujya mu bushakashatsi:

Nasomeye neza amakuru uwinjira mu bushakashatsi, nkurikije ubumenyi bwanjye nakoze ibishoboka byose ngo uwinjira mu bushakashatsi yumve neza aya makuru.

Ndemeza ko uwinjira mu bushakashatsi yahawe umwanya wo kubaza ibibazo ku bushakashatsi, kandi ko ibibazo byose byasubijwe neza. Ndemeza ko uwinjira mu bushakashatsi atahaswe kwemera kugira uruhare mu bushakashatsi, kandi ko byakozwe ku bushake kandi nta gahato.

Impapuro z'amakuru zahawe uwinjira mu bushakashatsi.

Izina ry'umushakashatsi/ uwemera gukorerwaho

ubushakashatsi_____

Umukono w'umushakashatsi/uwemeye gukorerwaho

ubushakashatsi_____

italiki_____

umunsi/ukwezi/umwaka

The budget of the study

Item	Quantity	Unit price (FRws)	Total price (FRws)	
1.	Printing of data collection forms	20	400 x20	16 000
2.	Communication (Airtime and Internet)			150.000
3.	Statistical data analysis by a Consultant Statistician	1	300.000	300000
4.	Home visit		300000	300000
5.	Nurses/medical students' compensation	3	100000	300000
6.	Printed copies of the draft/dissertation, 60 pages each	10x2copies	1.200	24.000
7.	Final printed copies of the dissertation, 60 pages each	10x2 copies	1.200	24.000
8.	Bookbinding	5x2 copies	5.000	50.000
	S/Total			1164000
	Miscellaneous 20%			232800
	Total			**1396800**

IRB Approval

UNIVERSITY OF RWANDA — COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 12th /11/2018

Dr NIYOMWUNGERI Reverien
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 379/CMHS IRB/2018

Your Project Title ***"Adherence to Antihypertensive Medications in the Primary Care Setting in Rwanda"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
			No (Reason)	
Name of Members	**Institute**	Yes	**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 24th October 2018, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/ www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 12th November 2018

Expiration date: The 12th November 2019

Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

Approval from MOH for data collection at Kabgayi

REPUBLIC OF RWANDA

Kigali, 24 JUIN 2019

N°20/3795/MIN/2019

MINISTRY OF HEALTH
P.O BOX 84 Kigali
www.moh.gov.rw

To Dr NIYOMWUNGERI Reverien
University of Rwanda
College of Medicine and Health Sciences
Resident Internal Medicine /PGY3
Email: niyorever@gmail.com
Cell phone :0783567285

Dear Dr.Niyomwungeri,

Re : Your request to carry out research in Kabgayi District Hospital

Reference is made to your letter dated 14 May 2019 which was requesting to conduct a research study on "***Adherence to antihypertensive medications in primary settings in Rwanda***" as a requirement of award of a Master's degree in Internal Medicine in Kabyayi Hospital ;

I am pleased to inform you that I have no objection concerning your data collection at Kabgayi District Hospital.

Please liaise with the management of Kabgayi Hospital for more guidance.

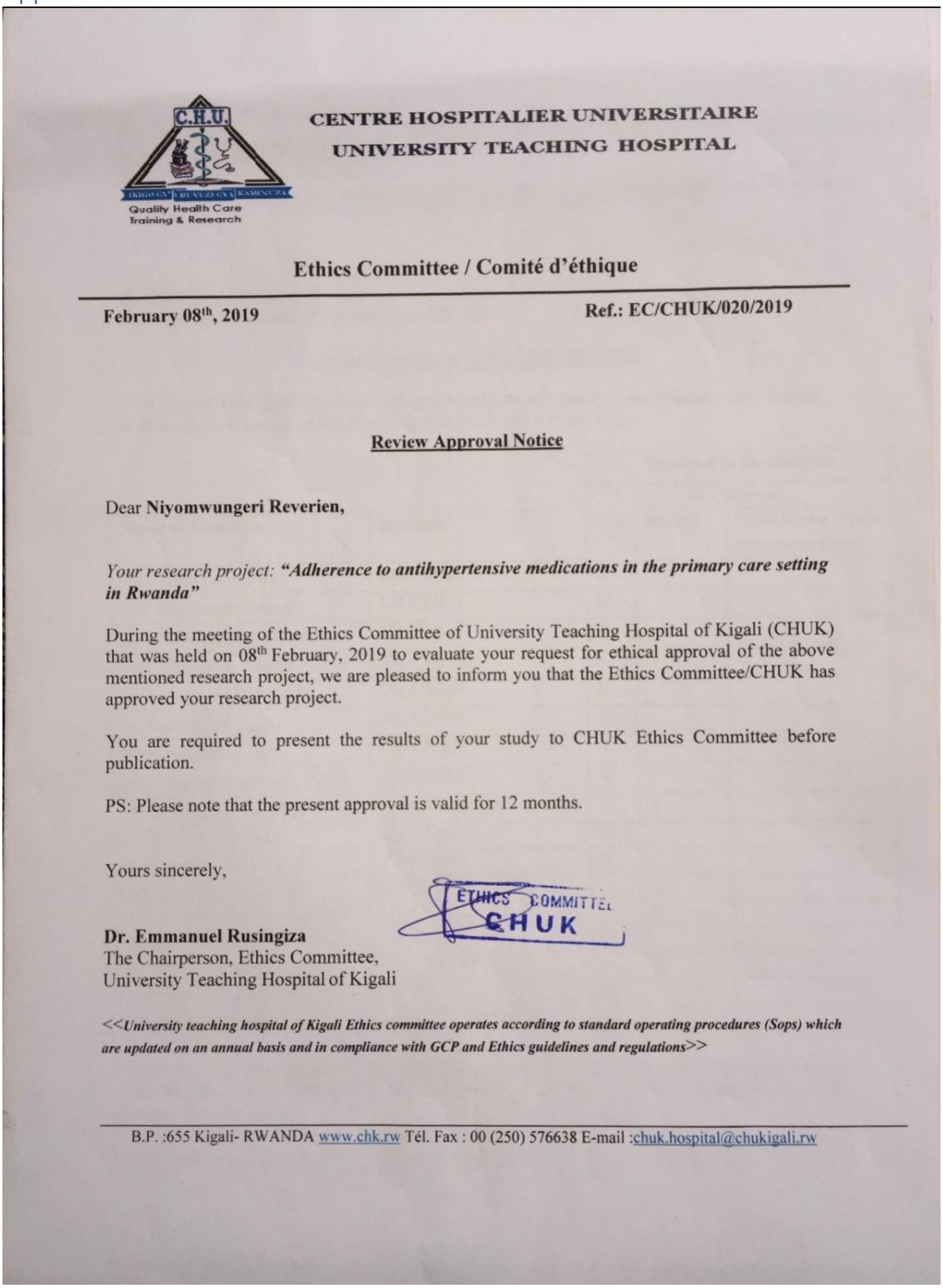
Sincerely,

MINISTERE DE LA SANTE

Dr. Diane GASHUMBA
Minister of Health

Cc:
The Dierctor of Kabgayi Hospital

Approval notice from CHUK



CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

February 08th, 2019 **Ref.: EC/CHUK/020/2019**

Review Approval Notice

Dear **Niyomwungeri Reverien,**

Your research project: ***"Adherence to antihypertensive medications in the primary care setting in Rwanda"***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 08th February, 2019 to evaluate your request for ethical approval of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

ETHICS COMMITTEE CHUK

Dr. Emmanuel Rusingiza
The Chairperson, Ethics Committee,
University Teaching Hospital of Kigali

<<University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations>>

B.P. :655 Kigali- RWANDA www.chk.rw Tél. Fax : 00 (250) 576638 E-mail :chuk.hospital@chukigali.rw