FACTORS, BELIEFS AND BARRIERS ASSOCIATED WITH ADHERENCE TO SECONDARY PROPHYLAXIS AMONGST CHILDREN AND ADOLESCENTS WITH RHEUMATIC HEART DISEASE AT PUBLIC TERTIARY HOSPITALS IN RWANDA – A CROSS-SECTIONAL STUDY

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FACTORS, BELIEFS AND BARRIERS ASSOCIATED WITH ADHERENCE TO SECONDARY PROPHYLAXIS AMONGST CHILDREN AND ADOLESCENTS WITH RHEUMATIC HEART DISEASE AT PUBLIC TERTIARY HOSPITALS IN RWANDA – A CROSS-SECTIONAL STUDY

By

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A dissertation submitted in partial fulfillment of the requirements for the degree of

MASTER OF MEDICINE IN GENERAL PEDIATRICS

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DECLARATION

I, Janvier DUSHIMIRE, hereby declare that this dissertation is my own work and to the best of my knowledge it contains no material previously published or written by another person except where specifically acknowledged.

Dr. Janvier DUSHIMIRE

10102893

Signed……………

July 2019
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I would like to express my gratitude to the Government of Rwanda through the Ministry of Health and the University of Rwanda for medical training and sponsorship. I am also thankful to all members of the Faculty Medicine and Pharmacy for knowledge transfer.

I thank and acknowledge my supervisor Dr. Emmanuel RUSINGIZA for his assistance and guidance in planning and conducting this research.

Special thanks are also due to CHUK and CHUB for allowing me to conduct this research and other referral hospitals for continuous training.

I acknowledge moral support and encouragement from my family.

I recognize the support from the pediatric residents especially classmates.

Lastly, I would like to thank parents and children who consented to participate in this study.
DEDICATION

I would like to dedicate this research project to my beloved parents, without their love, support and encouragement; I would not probably have gone this far in my postgraduate studies.

I also dedicate this work to my friends and colleagues, without them life in this program could not have been easy.
ABSTRACT

**Background:** Rheumatic Heart Disease continues to be a serious public health problem especially in developing countries and Sub-Saharan Africa in particular. Secondary prophylaxis with monthly Benzathine penicillin IM injection remains the most cost-effective strategy to reduce the morbidity and mortality. The efficiency of secondary prophylaxis using intramuscular penicillin depends largely on good adherence, yet not well known in many of the sub-Saharan countries including Rwanda. Our study aimed at determining the self-reported adherence rates in children and adolescents with RHD, determining the socioeconomic and demographic characteristics of patients with RHD on secondary prophylaxis and exploring factors, beliefs and barriers associated with adherence to secondary prophylaxis.

**Methods:** This was a cross-sectional study of 67 children and adolescents, aged 5 to 18 years, diagnosed with RHD presenting to two public tertiary hospitals in Rwanda; CHUK and CHUB either to the outpatient or inpatient department of pediatrics over a period of 5 months. The socio-demographic data, details about RHD prophylaxis were noted using a questionnaire. Good adherence was defined as patients receiving ≥ 80% of the expected injections in a period of 6 months. Statistical analysis to determine factors, barriers and beliefs associated with adherence was undertaken using multivariate logistic regression.

**Results:** The median age was 13.3 +/- 3 years, with 64.2% being females. Only 46.3% of participants had good adherence to secondary prophylaxis. The socioeconomic factors associated with good adherence were: having an employed parent/guardian (OR, 12.17; 95% CI, 1.42-103.9; p=0.022), living in urban area (OR, 9.05; 95% CI, 2.28-35.91; p=0.001), and having a parent/guardian with a high educational level (OR, 3.4; 95% CI, 1.15-10.12; p=0.027). Mostly encountered barriers to adherence are: long distance to the clinic (OR, 5.55; 95% CI, 1.94-15.89; p=0.001) and long waiting time at the clinic (OR, 4.77; 95% CI, 1.69-13.43; p=0.003).

**Conclusions and recommendations:** The level of adherence to secondary prophylaxis using intramuscular penicillin at tertiary level of care in Rwanda is very low. Education of patients and their caretakers along with reinforced decentralization of prevention at health centers should be enhanced for better adherence.

**Keywords:** Rheumatic Heart Disease; Medication Adherence; Child; Adolescent; Rwanda
LIST OF SYMBOLS AND ACCRONYMS

ARF- Acute Rheumatic Fever
CHUB- Centre Hospitalier Universitaire de Butare
CHUK - Centre Hospitalier Universitaire de Kigali
CMHS-College of Medicine and Health Sciences
EKG- Electrocardiogram
GAS- Group A streptococcus
IRB- Institutional Review Board
OPD – Out Patient Department
RHD- Rheumatic heart disease
UPI- Unique Patient Identifier
UR- University of Rwanda
HCP- Health Care Provider
WHO- World Health Organization
SPSS-Statistical Package for the Social Sciences
IBM-International Business Machines
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CHAPTER I. INTRODUCTION

I.1 BACKGROUND

Rheumatic Heart Disease (RHD) is the most common acquired cardiovascular disease in young people aged <25 years (1). Acute Rheumatic Fever (ARF) and RHD represent the first cause of cardiac mortality among children and young people in developing countries. It is the result of damage to the heart valves which occurs after repeated episodes of acute rheumatic fever. Acute rheumatic fever (ARF) is a post infectious, nonsuppurative sequel of pharyngeal infection with Group A beta hemolytic streptococcus infection (GAS) (2). ARF affects mainly the joint, the skin, the heart, and the central nervous system, the cardiac involvement leading to permanent valve damage. It commonly occurs between the ages of 4-15 years and takes place 2-3 weeks after GAS upper respiratory tract infection. The pathogenesis is not well understood but there is strong evidence that molecular mimicry between GAS antigen and human proteins lead to immune-mediated damage to heart valves.

Although ARF has almost disappeared in developed world due to improved sanitation and socioeconomic conditions, it continues to be a serious public health problem in developing countries (3). In Rwanda, RHD is a significant health problem with an estimated prevalence of 6.8 per 1000 school children (4). Once RHD occurs, there is a high rate of recurrence which leads to progressive valve damage and subsequently atrial fibrillation and heart failure (5,6). Advanced RHD requires expensive heart surgery and long life treatment and follow-up. Recurrence of ARF is the most important factor that determines the severity and prognosis of RHD (7).
Prevention of ARF includes primordial prevention which involves improving socioeconomic conditions; primary prevention involves prompt treatment of GAS pharyngitis; and secondary prevention which involves a continuous administration of benzathine penicillin G to patients with a previous attack of ARF, or well-documented RHD (7). Recurrent attacks of ARF and the progression of RHD can be prevented by prophylactic antibiotics with IM injection of benzathine penicillin G at three- to-four-week intervals (1). Alternatively, daily oral penicillin V can be given to a selected number of patients if compliance is guaranteed. However, even with optimal adherence, patients on oral penicillin have higher rates of non-adherence than those on benzathine penicillin G (8).

One factor that limits the efficacy of secondary prophylaxis programs is low patient adherence (6). Another intervention in prevention of early mortality due to RHD is cardiac surgery which is not accessible to many patients especially in low-income countries (9). Even after heart surgery, patients are exposed to many complication such as thrombo-embolic events and severe bleeding when using warfarin treatment (10). The cost-effective strategy remains prevention of ARF and progression to severe rheumatic valvular heart disease (11).

I.2. PROBLEM STATEMENT

They were approximately 33 million new cases of RHD in the year 2015, with an estimated 320,000 deaths; most of them occurred in endemic regions of East and South Asia and Sub-Saharan Africa (12). Rates have declined to near zero in nearly all developed countries due mainly to improvement in socio-economic status. However it continues to cause high morbidity and mortality in developing countries. Due to a very limited access to cardiac surgery in the resource-limited settings and the cost related to the surgical intervention, prevention remains the most cost-effective strategy to reduce mortality and morbidity due to RHD (9). Although based on low level of evidence, intramuscular penicillin was showed to be more effective than oral penicillin (8). The rate of adherence to secondary prophylaxis is unknown in many countries of sub-Saharan Africa and particularly in Rwanda. Different factors associated with adherence have been reported in various regions of the world. These include socioeconomic status, knowledge about the disease, waiting time at the clinic, the painful aspect of the injections, and distance to the clinic (1, 10).
Believing that the injections are effective, knowing the consequences of missing the injections, believing in traditional medications, trusting the information doctors provide had been associated with good or poor adherence (1).

Knowing different factors, beliefs and barriers associated with adherence would help clinicians finding ways of improving adherence to secondary prophylaxis and thus improve the quality of life of our patients.

I.3 AIM

The aim of this research project is to explore factors, beliefs and barriers associated with adherence to injectable form of penicillin in children and adolescents with RHD receiving secondary prophylaxis at public tertiary hospitals in Rwanda.

I.4 RESEARCH OBJECTIVES

1. To determine the self-reported adherence rates in children and adolescents with RHD
2. To determine the socioeconomic and demographic characteristics of patients with RHD on secondary prophylaxis
3. To explore factors, beliefs and barriers associated with adherence to secondary prophylaxis
CHAPTER II. LITERATURE REVIEW

Adherence has been defined as patients taking more than 80% of expected medication (13).

II.1. Medication adherence measures

According to the World Health Organization (WHO), adherence is “the extent to which the persons’ behavior (including medication taking) corresponds with agreed recommendations from a health care provider” (HCP) (14). Several tools are available and have been validated to measure adherence. These can be subjective or objective. Self-report and healthcare professional assessments are the most commonly used subjective tools of medication adherence evaluation (15). Self-report tools have a major disadvantage in that patients tend to under-report non-adherence to avoid disapproval from their healthcare providers.

Objective measures include pill counts, electronic monitoring, secondary database analysis, and biochemical measures (15).

II.2. Factors associated with adherence to RHD secondary prophylaxis

Previous studies assessing patient’s adherence to RHD secondary prophylaxis used clinician assessments and self-reports. Those studies have shown that non-adherence to secondary prophylaxis can be as high as 50% (1, 14). A study done in Uganda showed that 46% of patients were non-adherent to monthly benzathine penicillin and factors associated were living in a town/city for adherence and the painful aspect of the injection for non-adherence (13).

In Egypt, the rate of adherence to RHD prophylaxis was 65.5% and adherent patients had better understanding of the disease and were more aware of the consequences of missing penicillin injections (1).

A study done in India showed adherence of 52.2% and reasons for non-adherent were, among others, low socio-economic status, living in a rural area and being uneducated (3).

II.3. Barriers to RHD adherence to secondary prophylaxis

Attending the clinic monthly to get penicillin injections is not easy for many patients. Patient perceptions of illness, appreciation of the quality of care received, and cost associated with care are among the reported barriers to adherence (16).

On the other hand, painful injections, poor communication between HCP and patient, and unavailability of medications can affect negatively the adherence to RHD secondary prophylaxis.
Poor understanding of the disease and its prophylaxis combined with lack of family support have also negative impact the adherence (18). The absence of proper counseling and a sense of wellbeing have also been cited among reasons of not complying with prophylaxis (3).

II.4. Beliefs associated with RHD secondary prophylaxis

Adherence and engagement to a recommended medication may be influenced by a patient’s belief to that treatment (19). The finding of beliefs associated with an illness can serve as a potential intervention strategy (20). Perception of illness and hence knowledge of causality and severity of the disease play a large role when deciding to seek treatment (16).
CHAPTER. III METHODOLOGY

III.1. Study design, site, period, and population
This was a cross-sectional observational study of children and adolescents diagnosed with RHD presenting to two public tertiary hospitals in Rwanda (CHUK and CHUB) either to the outpatient or inpatient departments of pediatrics. CHUB receives most of patients referred from Southern Province and CHUK receives those from Northern, Western Provinces and Kigali City. Both hospitals provide cardiology services either by visiting or permanent cardiologist. Physicians and nurses are also among HCP that are involved in the follow-up of RHD patients. RHD Patients receive Penicillin prescriptions during their visits, either as oral or injection form. Most of injections are done near their respective hospitals or health centers, mostly rural. Data collection was carried out over a period of 5 months from January 2019 till May 2019. This study targeted children aged from 5 to 18 years old diagnosed with RHD on rheumatic heart disease who were receiving secondary prophylaxis for at least 6 months. The pediatric age in Rwanda health system is defined from 0 to 15 years. Those above 15 years of age are treated in Internal Medicine. However, most of those between 15 and 18 years continue to come in pediatrics for follow-up care after cardiac surgery.

III.2. Inclusion criteria
- Patients aged 5 to 18 years with confirmed RHD by echocardiography
- Patients who consent to participate
- RHD patients receiving monthly intramuscular (IM) penicillin injections
- Consulting two tertiary level hospitals (CHUK, CHUB) outpatient or admitted to pediatric cardiology ward.

III.3. Exclusion criteria
- Patients/guardians who decline to sign a consent/assent form
- Patients who have been on secondary prophylaxis for <6 months
- Patients who are on oral penicillin for prophylaxis
III.4. Sample size calculation

A sample size calculation has been calculated using Raosoft formula as follows:

\[ x = \frac{Z(c/100)^2r(100-r)}{n} \]

\[ n = \frac{N^x}{(N-1)E^2 + x} \]

\[ E = \sqrt{\left(\frac{N-n}{n(N-1)}\right)} \]

Where:

E is the margin of error and is of about 5%

N is the population size, in this case it is 80, the total number of patients received in pediatric outpatient in a period of 4 months

r is the fraction of response we are interested in, in this case 54% based on a study done in Uganda(13).

Z(c/100) is the critical value for the confidence level c, 95% confidence interval.

n is the sample size and equal to 67, aiming to get greater numbers from one study site than others.

III.5. Sampling

Patients who fulfilled the inclusion criteria were opportunistically enrolled when they attended OPD-pediatric cardiology or when they are admitted to pediatric cardiology ward. Those who did not frequently attend the clinics at the study sites were contacted by telephone using a hospital registry.

III.6. Data collection tool and procedure

Data was collected using a questionnaire. We used a modified questionnaire developed by Balbaa et al in Egypt in 2015 (1). The questionnaire was chosen because there are no previous tools that have assessed self-reported adherence in medications such as monthly IM penicillin
injection. The other reason was that it has been implemented in a setting which was not too dissimilar to Rwanda.

The questionnaire consists of 4 sections: the socioeconomic status including level of education, employment status and the economic class; the adherence self-reporting; clinical characteristics of ARF/RHD and its prophylaxis; and 17 Likert scale questions on RHD beliefs and treatment barriers. Other questions were: understanding the disease and its complications, medication side effects, waiting time at the clinic, time since the start of prophylaxis, barriers to adherence and the duration of prophylaxis, etc. The economic classes follow ubudehe categories where households are put in categories based on their social-economic status, and their poverty- in terms of land and belongings- and what families’ breadwinners do to earn a living. The categories are counted from 1 to 4.

The questionnaire has been translated in the local language (Kinyarwanda) by a certified translator to facilitate its understanding by the subjects. The questionnaire was then back-translated by a medical professional. The translated questionnaire was then piloted on three participants, with modification of the questionnaires to ensure better understanding. Patients who participated in pilot were not allowed to participate in the main study to avoid recall bias.

Data was collected by the Principal Investigator (PI). Some patients were met at OPD while coming during their scheduled follow-up or penicillin injections. Others were found when they were admitted to the hospital. Participants who did not regularly attend the clinic at the study sites were contacted by telephone after checking their personal contacts in their medical files or hospital registry.

The participants, together with their caretakers, who met the PI, received the information on the ongoing study, and were invited to ask questions for clarifications and requested to sign a written consent and/or assent form. The consent form was signed by the parent or guardian while the assent form was only signed by children aged 11 years and above. Upon signing a consent/assent form, participants were requested to answer questions on the questionnaire by the data collector. Upon completion of the questionnaires, they were checked by the investigator for completeness and kept in the drawer waiting to be entered in the database.
Patients, who were contacted by telephone, were requested to give a verbal consent and the questionnaire was administered by telephone by the Principal Investigator.

Data were entered in Epidata version 3.1 by the principal investigator and coded for analysis.

### III.7. Data analysis

After entering patient information in Epidata 3.1, data were exported to IBM SPSS Statistics version 25 for statistical analysis. For descriptive analysis, continuous variables were summarized in means and median. Categorical data were summarized using frequency and percentages.

The adherence rate for individual patients was calculated by dividing the number of injections of benzathine penicillin G by the number of expected injections in a period of 6 months.

For factors associated with adherence, bivariate analysis was undertaken using Logistic regression where Odds Ratios were calculated. A multivariate logistic regression analysis was undertaken to minimize for confounding and to determine which independent variables are associated with the poor compliance. Variables were included in the multivariate analysis if they had a p-value <0.05 from the bivariate analysis. The final multivariate analysis was described using odds ratios and p-values.

Likert scale questions were described using means and standard errors. Comparison of Likert questions was undertaken to compare differences in scores between participants with good and bad adherence. The Likert score data were normally distributed and therefore were analyzed using Independent sample t-test. The 17 Likert questions fell into two categories of questions, barriers and beliefs which were used to compare the scores of participants with good adherence and score of participants with bad adherence.

### III.8. Ethical consideration

Permission to conduct this study was obtained from University of Rwanda (UR), College of Medicine and Health Sciences (CMHS)-Institutional Review Board (Approval notice: No.377/CMHS IRB/2018). We also got permission from CHUK (Ref.:EC/CHUK/736/2018) and CHUB (RC/UTHB/051/2018) Research and Ethics Committees. Participants signed a written consent and their participation was voluntary. Those who did not attend clinics during the study period gave an oral consent by telephone. No incentive to participate in this study
CHAPTER IV. RESULTS

IV.1. Socio-demographic characteristics of the study population
A total sample of 67 participants meeting the inclusion criteria was interviewed in the study. The median age was 13.3 +/- 3 years, (IQR 11-16) with 64.2% (N=43) being females. The majority of participants (82.1%, N=55) were recruited from CHUK and the remaining from CHUB. Most of participants (74.6%, N=50) live in rural area and the majority (64.1%, N=43) come from poor families and belong to Ubudehe category 1 and 2. 46.3% (N=31) of guardians/caretakers completed only primary education and only 13.4% (N=9) of parents/guardians have a formal job.
Table 1: Socio-demographic characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD)</td>
<td>13.3 ± 2.7 years</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>43</td>
<td>64.2</td>
</tr>
<tr>
<td>Male</td>
<td>24</td>
<td>35.8</td>
</tr>
<tr>
<td>Place of recruitment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHUK</td>
<td>55</td>
<td>82.1</td>
</tr>
<tr>
<td>CHUB</td>
<td>12</td>
<td>17.9</td>
</tr>
<tr>
<td>Economic class (Ubudehe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1</td>
<td>7</td>
<td>10.4</td>
</tr>
<tr>
<td>Category 2</td>
<td>36</td>
<td>53.7</td>
</tr>
<tr>
<td>Category 3</td>
<td>24</td>
<td>35.8</td>
</tr>
<tr>
<td>Time since diagnosis was made</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5 years ago</td>
<td>50</td>
<td>74.6</td>
</tr>
<tr>
<td>&gt;5 years</td>
<td>17</td>
<td>25.4</td>
</tr>
<tr>
<td>Employment status of caretaker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>9</td>
<td>13.4</td>
</tr>
<tr>
<td>Unemployed</td>
<td>58</td>
<td>86.6</td>
</tr>
<tr>
<td>Address</td>
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<td></td>
</tr>
<tr>
<td>Urban</td>
<td>17</td>
<td>25.4</td>
</tr>
<tr>
<td>Rural</td>
<td>50</td>
<td>74.6</td>
</tr>
<tr>
<td>Recruitment setting</td>
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<td></td>
</tr>
<tr>
<td>OPD</td>
<td>65</td>
<td>97.0</td>
</tr>
<tr>
<td>Inpatient</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td>Level of education of participant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary completed</td>
<td>39</td>
<td>58.2</td>
</tr>
<tr>
<td>None</td>
<td>28</td>
<td>41.8</td>
</tr>
<tr>
<td>Level of education of parent/caretaker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University completed</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>High school completed</td>
<td>9</td>
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<tr>
<td>Vocational completed</td>
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<td>16.4</td>
</tr>
<tr>
<td>Primary completed</td>
<td>31</td>
<td>46.3</td>
</tr>
<tr>
<td>None</td>
<td>15</td>
<td>22.4</td>
</tr>
</tbody>
</table>
IV.2. Rheumatic heart disease management
This study shows that only 46.3% (N=31) received ≥ 80% of the due injections in the previous 6 months. Most patients (67.2%, N=45) admitted that whenever they miss an appointment, they go a few days later while others wait until the next appointment to go to the clinic. A greater proportion of participants (59.7%, N=40) are unaware of the side effects of penicillin injections and no single patient have experienced a bad reaction apart from pain and swelling at the site of injection. 76.1% (N=51) of the study population believe that their disease would get worse if they missed some injections while 23.9% (N=16) think that missing some injections would not have a negative impact on their health.

92.5% of participants (N=62) travel between 1 to 3 hours to reach the clinic and 85.1% (N=57) wait between 40 minutes and 2 hours at the clinic to meet the healthcare provider. 88.1% (N=59) of the interviewed patients believe that penicillin injections can stop the progression of RHD while 11.9% (N=9) believe that it has no effect on disease progression. Nearly all participants (95.5%) do not trust traditional medications.

IV.3. Socioeconomic factors associated with adherence
Table 2 shows the socioeconomic factors associated with adherence to RHD secondary prophylaxis. There is a strong association between employment status of the parent/guardian and adherence whereby having an employed parent/guardian is associated with good adherence (OR [95% CI]: 12.17[1.42-103.9], p=0.022). Living in urban area also makes somebody adherent to RHD secondary prophylaxis than being from a rural area (OR [95% CI]: 9.05[(2.28-35.91, p=0.001].

The table below also shows that having a parent/guardian with a high educational level is associated with good adherence (OR [95% CI]: 3.4 [1.15-10.12], p=0.027).
Table 2. Socioeconomic factors associated with adherence to RHD secondary prophylaxis

<table>
<thead>
<tr>
<th>Socio-economic variables</th>
<th>Self-reported adherence</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adherent</td>
<td>Non-adherent</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>20 (46.5%)</td>
<td>23 (53.5%)</td>
<td>1.02 (0.37-2.79)</td>
</tr>
<tr>
<td>Male</td>
<td>11 (45.8%)</td>
<td>13 (54.2%)</td>
<td></td>
</tr>
<tr>
<td><strong>Home address</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>14 (82.4%)</td>
<td>3 (17.6%)</td>
<td>9.05 (2.28-35.91)</td>
</tr>
<tr>
<td>Rural</td>
<td>17 (34.0%)</td>
<td>33 (66.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Employment status of parent/guardian</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>8 (88.9%)</td>
<td>1 (11.1%)</td>
<td>12.17 (1.42-103.9)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>23 (39.7%)</td>
<td>35 (60.3%)</td>
<td></td>
</tr>
<tr>
<td><strong>Who accompanies the patient to the clinic?</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>5 (26.3%)</td>
<td>14 (73.7%)</td>
<td></td>
</tr>
<tr>
<td>Family member</td>
<td>26 (54.2%)</td>
<td>22 (45.8%)</td>
<td>3.31 (1.02-10.64)</td>
</tr>
<tr>
<td><strong>Level of education of parent/guardian</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary/University</td>
<td>14 (66.7%)</td>
<td>7 (33.3%)</td>
<td>3.4 (1.15-10.12)</td>
</tr>
<tr>
<td>Primary/None</td>
<td>17 (37.0%)</td>
<td>29 (63.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Economic class (Ubudehe)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1&amp;2</td>
<td>16 (37.2%)</td>
<td>27 (62.8%)</td>
<td></td>
</tr>
<tr>
<td>Category 3</td>
<td>15 (62.5%)</td>
<td>9 (37.5%)</td>
<td>2.81 (1.0-7.89)</td>
</tr>
</tbody>
</table>

IV.4. Barriers, beliefs and behaviors associated with adherence

Table 3 shows some barriers, beliefs and behaviors associated with adherence to secondary prophylaxis. Long distance to the clinic was shown to be strongly associated with poor adherence (OR [95% CI]: 5.55 [1.94-15.89], p=0.001). The table also shows an association between long waiting time at the clinic with poor adherence (OR [95% CI]: 4.77 [1.69-13.43], p=0.003).
### Table 3. Barriers, beliefs and behaviors associated with adherence

<table>
<thead>
<tr>
<th>Barriers, beliefs and behaviors</th>
<th>Self-reported adherence</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adherent</td>
<td>Non-adherent</td>
<td></td>
</tr>
<tr>
<td>Long distance to the clinic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9 (26.5%)</td>
<td>25 (73.5%)</td>
<td>5.55 (1.94-15.89)</td>
</tr>
<tr>
<td>No</td>
<td>22 (66.7%)</td>
<td>11 (33.3%)</td>
<td></td>
</tr>
<tr>
<td>Long waiting time at the clinic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10 (28.6%)</td>
<td>25 (71.4%)</td>
<td>4.77 (1.69-13.43)</td>
</tr>
<tr>
<td>No</td>
<td>21 (65.6%)</td>
<td>11 (34.4%)</td>
<td></td>
</tr>
<tr>
<td>Awareness of side effects of the injections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>17 (42.5%)</td>
<td>23 (57.5%)</td>
<td>0.68 (0.25-1.83)</td>
</tr>
<tr>
<td>No</td>
<td>14 (51.9%)</td>
<td>13 (48.1%)</td>
<td></td>
</tr>
<tr>
<td>Consequences of not getting the injections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Worsening my heart condition</td>
<td>27 (52.9%)</td>
<td>24 (47.1%)</td>
<td>3.37 (0.95-11.87)</td>
</tr>
<tr>
<td>It's ok, nothing will happen</td>
<td>4 (25.0%)</td>
<td>12 (75.0%)</td>
<td></td>
</tr>
<tr>
<td>Awareness of possible surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>24 (42.9%)</td>
<td>32 (57.1%)</td>
<td>0.43 (0.11-1.63)</td>
</tr>
<tr>
<td>No</td>
<td>7 (63.6%)</td>
<td>4 (36.4%)</td>
<td></td>
</tr>
<tr>
<td>Knowledge of the role of secondary prophylaxis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>26 (44.1%)</td>
<td>33 (55.9%)</td>
<td>0.63 (0.15-2.58)</td>
</tr>
<tr>
<td>No</td>
<td>5 (62.5%)</td>
<td>3 (37.5%)</td>
<td></td>
</tr>
<tr>
<td>Belief in traditional healers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (100%)</td>
<td>0 (0.0%)</td>
<td>8.96 (0.44-180.7)</td>
</tr>
<tr>
<td>No</td>
<td>28 (43.8%)</td>
<td>36 (56.3%)</td>
<td></td>
</tr>
</tbody>
</table>

### IV.5. Relationship between barriers and beliefs with adherence

Table 4 below highlights the difference between adherent and non-adherent patients according to their beliefs and barriers. It shows that patients with good adherence have a higher score of beliefs than those with poor adherence (M±SE: 1.56 ± 0.54, t=2.878, p=0.005). Moreover, patients with a high score of barriers are less adherent than those with low score (M±SE: 4.6 ± 0.85, t=5.531, p<0.001).
### Table 4. Comparison of beliefs and barriers scores among adherence groups

<table>
<thead>
<tr>
<th>Score</th>
<th>Adherence (M ± SE)</th>
<th>Mean difference (M ± SE)</th>
<th>95% CI</th>
<th>T-test</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adherent</td>
<td>Non-Adherent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total beliefs score/40</td>
<td>32.26 ± 0.45</td>
<td>30.7 ± 0.32</td>
<td>1.56 ± 0.54</td>
<td>0.48-2.64</td>
<td>2.878</td>
</tr>
<tr>
<td>Mean beliefs score/5</td>
<td>4.03 ± 0.56</td>
<td>3.83 ± 0.04</td>
<td>0.19 ± 0.07</td>
<td>0.05-0.33</td>
<td>2.878</td>
</tr>
<tr>
<td>Total barriers score/45</td>
<td>26.58 ± 0.64</td>
<td>31.28 ± 0.56</td>
<td>4.6 ± 0.85</td>
<td>6.39-3.0</td>
<td>5.531</td>
</tr>
<tr>
<td>Mean barriers score/5</td>
<td>2.95 ± 0.07</td>
<td>3.47 ± 0.06</td>
<td>0.52 ± 0.09</td>
<td>0.71-0.33</td>
<td>5.531</td>
</tr>
</tbody>
</table>
CHAPTER V. DISCUSSION

This study aimed at exploring factors, beliefs and barriers associated with adherence to injectable penicillin in children and adolescents with RHD. The majority of patients (64.2%) were females, and the mean age of participants was 13.3 +/- 3 years. These findings are similar to those in other studies done elsewhere, for instance in Uganda, Jamaica and India where females represented 78.9%, 74.4% and 54% respectively (3,13,19).

Most of our patients live in rural area (74.6%), similar to findings in India (69%) and Uganda (60%). However, in Egypt, most patients were predominantly coming from semi-urban or urban area (1,3,13).

The majority of our patients (61.4%) come from poor families as most of them belong to social class Ubudehe category 1 and 2. The Indian study showed that 73.6% of their patients had low socioeconomic status (3). In the Ugandan study, only 68.4% of patients were not employed (13). However, in Lifou, New Caledonia, Gasse at al showed that a great proportion of households in their study had a high level of income per month (22). Moreover, only 13.4% of our patients’ guardians/caretakers have a formal job whereas a study done by S. Thompson et al, in Jamaica, found that 35% of their patients were unemployed (21).

The majority (46.3%) of our patients’ guardians/caretakers completed only primary education. These findings are similar to those of C. Musoke et al; 46.3% (which was the majority) of their patients were also having a primary level of education (13). Conversely, a study in India found that 65% of participants in their study were educated (3).

Antibiotic prophylaxis against recurrent episodes of acute rheumatic fever has been shown to be a feasible, cost-effective measure to eradicate RHD. The present study showed a low adherence to secondary prophylaxis using intramuscular penicillin among patients attending two referral hospitals in our country (46.3%). This is had been the same case in previous studies looking at rates of adherence especially in low-income countries. Respicio and Sicat found adherence to be 46.6% in their study in Philippines(23). Adherence also was 48.7% in a study done in Jamaica (21). In the Northern Territory of Australia, the adherence was 56% (24) and 58% in Uganda(25). Non-adherence was found to be 35% of Brazilian children(26).
In our study, low adherence to secondary prophylaxis was more associated with having an unemployed parent/guardian, living in a rural area, and being from a parent/guardian with low educational level (p=0.022, p=0.001, p=0.027 respectively). Similar findings have been found by researchers in other parts of the world. In Egypt, non-adherence to secondary prophylaxis was more common in children whose parents had lower educational and occupational levels (27). The same findings were seen in Uganda where residence in a city and at least a secondary level of education were associated with a better adherence(28). In Fiji, urban residence was associated with good adherence (29).

Barriers associated with low adherence in our study were reported to be long distance to the clinic and long waiting time to the clinic. A study done in Jamaica came to the same conclusions in addition to fearing the painful aspect of the injections and having to be absent from school to go to the clinic (21). Apart from distance to the clinic, costs associated with care, and patient perceptions of illness were cited among barriers to adherence to RHD secondary prophylaxis(16).

**Study strengths and limitations of the study**

Our study is the first looking at factors, beliefs and barriers associated with the adherence to secondary prophylaxis in children with RHD in Rwanda. However, it is subject to limitations such as the nature of the study where self-reporting of adherence is prone to acquiescence bias, whereby participants give the answers that they feel the researcher wants to hear. Ours was more prone to acquiescence bias as the principal investigator completed the questionnaire for the participants but we tried to balance this by ensuring that participants understand fully the questions by keeping them short and clear. Additionally, this study was done on a small sample size and at a specific site; hence results should not be generalized.
CHAPTER VI. CONCLUSION AND RECOMMENDATIONS

Adherence to secondary prophylaxis has been shown to be the most effective way to reduce mortality and morbidity associated with RHD. The adherence to RHD secondary prophylaxis using injectable penicillin at a tertiary level of care in Rwanda is found to be low. Having a non-employed parent, and living in a rural area were factors mostly affected with poor adherence. Long distance to the clinic and long waiting time at the clinic were cited among the most commonly encountered barriers to adherence.

To improve adherence to secondary prophylaxis in patients with RHD, the following recommendations should be considered:

1. Education of RHD patients and their parents/caretakers should be reinforced, emphasizing on the importance to adhere to secondary prophylaxis.
2. Decentralization of RHD prevention activities should be implemented in all health centers.
3. RHD registries and Benzathine penicillin injection cards are needed in order to improve adherence records and identify patients needing support to improve their level of adherence.
4. Conduct a wide study on a bigger sample size to determine the level of adherence to secondary prophylaxis in Rwanda.
REFERENCES


APPENDICES

APPENDIX 1.SEARCH TERMS

Search terms (MeSH terms in italics)

(adherence OR patient compliance OR compliance)

AND (secondary antibiotic prophylaxis or prevention and control)

AND (Administration, oral OR oral OR administration, intravenous OR intravenous OR administration)

AND (Child OR children OR pediatrics OR pediatric OR paediatric*)

AND (Developing Countries OR developing country OR countries, developing OR developing nations OR Poverty OR resource poor country OR low income country OR low-income country OR resource-poor country OR Global Health OR third word OR India OR Africa OR Asia OR South America OR Papua New Guinea OR Asia-Pacific)

LIMITS No limits were applied

Search date July 24, 2018
APPENDIX 2. SAMPLE SIZE CALCULATION FORMULA

\[
x = Z_{(c/100)}^2 \times (100-r)
\]

\[
n = \frac{N \times r \times (100-r)}{(N-1)E^2 + x}
\]

\[
E = \text{Sqrt} \left[ \frac{(N-n)x}{n(N-1)} \right]
\]

Where:

E is the margin of error and is of about 5%

N is the population size, in this case it is 80, the total number of patients received in pediatric outpatient in a period of 4 months

r is the fraction of response we are interested in, in this case 54% based on a study done in Uganda(13).

Z(c/100) is the critical value for the confidence level c, 95% confidence interval.

n is the sample size and equal to 67, aiming to get greater numbers from one study site than others.
APPENDIX 3.DATA COLLECTION TOOL-ENGLISH

“Factors, beliefs and barriers associated with adherence to secondary prophylaxis amongst children with rheumatic heart disease at public tertiary hospitals in Rwanda”-a cross-sectional study

<table>
<thead>
<tr>
<th>Study ID:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Place of recruitment</td>
<td>[ ] CHUK [ ] CHUB [ ] RMH</td>
</tr>
<tr>
<td>Setting</td>
<td>[ ] OPD [ ] IP</td>
</tr>
</tbody>
</table>

I. Demographic data

<table>
<thead>
<tr>
<th>Gender</th>
<th>[ ] Male [ ] Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of birth</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td>Province: .................District: .................Sector: .................</td>
</tr>
<tr>
<td>I attend clinics</td>
<td>[ ] Alone [ ] With a family member</td>
</tr>
<tr>
<td>If with a family member, what is the relationship to the patient?</td>
<td>[ ] parent, [ ] sibling, [ ] other relative, [ ] friend, [ ] other</td>
</tr>
</tbody>
</table>

II. Socioeconomic status

<table>
<thead>
<tr>
<th>Level of education</th>
<th>[ ] College/University completed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[ ] High school completed</td>
</tr>
<tr>
<td></td>
<td>[ ] Vocational completed</td>
</tr>
<tr>
<td></td>
<td>[ ] Primary completed</td>
</tr>
<tr>
<td></td>
<td>[ ] None</td>
</tr>
<tr>
<td>Level of education of parents/caretakers</td>
<td></td>
</tr>
<tr>
<td>College/University completed</td>
<td>[ ]</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>High school completed</td>
<td>[ ]</td>
</tr>
<tr>
<td>Vocational completed</td>
<td>[ ]</td>
</tr>
<tr>
<td>Primary completed</td>
<td>[ ]</td>
</tr>
<tr>
<td>None</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Employment status of parents/caretakers**

- [ ] Employed
- [ ] Unemployed

**Ubudehe category**

- [ ] Category 1
- [ ] Category 2
- [ ] Category 3
- [ ] Category 4

**Health insurance**

- [ ] Yes
- [ ] No

**III. Rheumatic heart disease**

**Do you know your diagnosis?**

- [ ] Yes
- [ ] No

**When was it diagnosed?**

- [ ] 0-5 years ago
- [ ] >5 years ago

**Rheumatic heart disease (tick all that apply)**

- [ ] can cause cancer
- [ ] can cause weakness of the heart valves
- [ ] can cause high blood pressure
- [ ] can sometimes cause no symptoms
- [ ] can cause palpitations
- [ ] if left untreated can lead to serious complications
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>When did you start prophylaxis?</td>
<td>[ ] unsure</td>
</tr>
<tr>
<td></td>
<td>[ ] Less than 1 year, [ ] 1-2 years [ ] 2-5 years [ ] &gt;5 years ago</td>
</tr>
<tr>
<td>Does anyone in your immediate family has RHD?</td>
<td>[ ] Yes [ ] No</td>
</tr>
<tr>
<td>Did you miss any injections in the last 6 months?</td>
<td>[ ] Yes [ ] No</td>
</tr>
<tr>
<td>If yes, how many?</td>
<td>[ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6</td>
</tr>
<tr>
<td>If I miss an appointment</td>
<td>[ ] I wait until the next appointment</td>
</tr>
<tr>
<td></td>
<td>[ ] I go a few days later</td>
</tr>
<tr>
<td>I am aware of the side effects of the injections</td>
<td>[ ] Yes [ ] No</td>
</tr>
<tr>
<td>If I do not get these injections</td>
<td>[ ] my heart condition will get worse</td>
</tr>
<tr>
<td></td>
<td>[ ] it’s ok to miss some doses, nothing will happen</td>
</tr>
<tr>
<td>I am aware that I might need surgery</td>
<td>[ ] Yes [ ] No</td>
</tr>
<tr>
<td>How long do you usually wait at the clinic?</td>
<td>[ ] 20 min [ ] 20–40 min [ ] 40–60 min [ ] 1–2 hours [ ] 2 hours</td>
</tr>
<tr>
<td>I will need to continue these injections for many years:</td>
<td>[ ] True [ ] False</td>
</tr>
<tr>
<td>I am aware that these injections can stop the progression of Rheumatic heart disease:</td>
<td>[ ] Yes [ ] No</td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>Do you believe that there is a more effective traditional medicine to treat RHD?</td>
<td></td>
</tr>
<tr>
<td>Have you ever been hospitalized because of your condition?</td>
<td></td>
</tr>
<tr>
<td>Have you ever had a bad reaction (more than local swelling and tenderness) following a previous penicillin injection?</td>
<td></td>
</tr>
<tr>
<td>How long does it take you to get to the clinic?</td>
<td>1</td>
</tr>
<tr>
<td>more than 5 hours</td>
<td>3</td>
</tr>
<tr>
<td>What mode of transportation do you use to get to the clinic?</td>
<td>4</td>
</tr>
<tr>
<td>When you miss an appointment, it is because:</td>
<td>6</td>
</tr>
<tr>
<td>you forgot</td>
<td></td>
</tr>
<tr>
<td>you consciously choose to/ were unable to make it</td>
<td></td>
</tr>
<tr>
<td>other reasons</td>
<td></td>
</tr>
</tbody>
</table>
DIRECTIONS: Please complete the following items on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree) by encircling the number in the box that best describes you. REMEMBER: There is no right or wrong answer.

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Undecided</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My doctor has explained what Rheumatic heart disease is.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. My doctor clarified why the injections are important.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. I believe that this medication is effective.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. I need to take this medication even if I do not feel any symptoms.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Taking the injections will make me better.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Members of my family remind me to go for my appointment.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. I trust the information the doctors provide.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. I want to come to the clinic on a regular basis but am unable to.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. Coming to these clinic visits is worth my time and effort.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10. My number one priority is making it to my scheduled clinic appointments.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. Taking the injections makes me feel unwell.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. Taking the injections is painful.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. The painful nature of the injection</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>14. The distance to the clinic is a deterrent to attend appointments.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. Costs associated to coming to the clinic (days of work, transportation, etc.) prevent me from coming.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16. It is difficult to keep track of appointment times.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. Long wait times at the clinic are a deterrent to come to my appointment.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
**APPENDIX 4. DATA COLLECTION TOOL-KINYARWANDA**

Imyumvire n’imbogamizi bijyanye no gutanga uburinzi bw’ inyongera ku bana bafite indwara y’ umutima ikomoka kuri gapfura mu bitaro bikuru byo mu Rwanda

<table>
<thead>
<tr>
<th>Nomero y’ubushakashatsi</th>
<th>[ ] CHUK [ ] CHUB [ ] RMH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahakorewe ubushakashatsi:</td>
<td>[ ] OPD [ ] IP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I. Umwirondoro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Igitsina</td>
</tr>
<tr>
<td>Itariki yamavuko</td>
</tr>
<tr>
<td>Aho akomoka</td>
</tr>
</tbody>
</table>

| Nza kwa muganga | [ ] Ndi n'nyenyine [ ] Mperekeje n’umuntu wo mu muryango |

| Niba uba uri kumwe n’umuntu wo mu muryango, ni iyihe sano afitanye n’umurwayi? | [ ] Umubyeyi, [ ] Umuvandimwe, [ ] indi sano, [ ] inshuti, [ ] undi |

<table>
<thead>
<tr>
<th>II. Amashuri</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urwego rw’amashuri yize</td>
</tr>
</tbody>
</table>

| [ ] Yasoje amashuri yisumbuye |
| [ ] Yasoje mu ishuri ry’ imyuga |
| [ ] Yasoje amashuri abanza |
| [ ] Nta na hamwe |

<table>
<thead>
<tr>
<th>Urwego rw’amashuri umubyeyi/ umurwaza yize</th>
</tr>
</thead>
</table>

<p>| [ ] Yasoje mu Ishuri rikuru/ Kaminuza |
| [ ] Yasoje amashuri yisumbuye |
| [ ] Yasoje mu ishuri ry’ imyuga |
| [ ] Yasoje amashuri abanza |
| [ ] Nta na hamwe |</p>
<table>
<thead>
<tr>
<th>Icyo umubyeyi/ umurwaza akora</th>
<th>[ ] Afite akazi</th>
<th>[ ] Nta kazi afite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Icyiciro cy’ Ubudehe</td>
<td>[ ] Icyiciro cya 1</td>
<td>[ ] Icyiciro cya 2</td>
</tr>
<tr>
<td>[ ] Icyiciro cya 3</td>
<td>[ ] Icyiciro cya 4</td>
<td></td>
</tr>
<tr>
<td>Afite Ubwishingizi</td>
<td>[ ] Yego</td>
<td>[ ] Oya</td>
</tr>
</tbody>
</table>

III. Indwara y’umutima ikomoka kuri gapfura

<table>
<thead>
<tr>
<th>Ese waba uzi uburwayi ufite?</th>
<th>[ ] Yego</th>
<th>[ ] Oya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indwara y’umutima iterwa na gapfura (Vivura aho usanga ari ngombwa hose)</td>
<td>[ ] ishobora gutera kanseri</td>
<td>[ ] ishobora gutuma imihera yumutima icika intege.</td>
</tr>
<tr>
<td>[ ] ishobora gutuma imihera yumutima icika intege.</td>
<td>[ ] Rimwe na rimwe ishobora kutagaragara.</td>
<td></td>
</tr>
<tr>
<td>[ ] ishobora gutuma habaho gutengurwa.</td>
<td>[ ] itavuwe ishobora guteza ibyago bikabije</td>
<td></td>
</tr>
<tr>
<td>[ ] simbizi neza</td>
<td>[ ] muni y’umwaka umwe, [ ] hagati y’umwaka umwe n’ imyaka ibiri [ ] hagati y’imyaka ibiri n’imyaka itanu [ ] hejuru y’imyaka itanu ishize.</td>
<td></td>
</tr>
</tbody>
</table>

Hari umuntu mu muryango wanyu urwaye indwara y’umutima iterwa na gapfura?

| Hari hari inshinge utigeze utaterwa mu meze 6 ashize? | [ ] Yego | [ ] Oya |

Niba ari yego, ni zingahe?

| [ ] 1 | [ ] 2 | [ ] 3 | [ ] 4 | [ ] 5 | [ ] 6 |

Iyo ntabonanye na muganga ku muns | [ ] ndategereza gahunda itaha |
<table>
<thead>
<tr>
<th>yampaye</th>
<th>[ ] Nsubirayo nyuma yiminsi mike</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nzi ingaruka inshinge zishobora gutera.</td>
<td>[ ] Yego [ ] Oya</td>
</tr>
<tr>
<td>Iyo ntafashe izo nshinge</td>
<td>[ ] Umutima wanjye umererwa nabi</td>
</tr>
<tr>
<td>Nzi ko bishobora kuba ngombwa ko mbagwa</td>
<td>[ ] Yego [ ] Oya</td>
</tr>
<tr>
<td>Utegereza igihe kingana iki kwa muganga?</td>
<td>[ ] Isaha 1, [ ] hagati y’isaha 1 n’amasaha 3, [ ] hagati y’amasaha 3 n’amasaha 5 [ ] hejuru yamasaha 5</td>
</tr>
<tr>
<td>Nkeneye gukomeza gufata izi nshinge imyaka myinshi</td>
<td>[ ] ni byo [ ] Si byo</td>
</tr>
<tr>
<td>Ndabizi ko izi nshinge zishobora gutuma indwara y’ umutima iterwa na gapfura idakomera:</td>
<td>[ ] Yes [ ] No</td>
</tr>
<tr>
<td>Ese hari umuti gakondo wizera ko wavura indwara y’ umutima iterwa na gapfura?</td>
<td>[ ] Yego [ ] Oya</td>
</tr>
<tr>
<td>Wigeze na rimwe ujyanwa mu bitaro kubera iyi ndwara?</td>
<td>[ ] Yego [ ] Oya</td>
</tr>
<tr>
<td>Ese wigeze ugirwaho ingaruka ( uretse kubyimba no kubabara) n’urunshinge uterwa buri kwezi?</td>
<td>[ ] Yego [ ] Oya</td>
</tr>
<tr>
<td>Bitwara igihe kingana iki kujya kwa muganga?</td>
<td>[ ] iminota 20 [ ] hagati y’iminota 20 na 40 [ ] hagati y’iminota 40 na 60 [ ] hagati y’isaha n’amasaha 2 [ ] amasaha 2 [ ]</td>
</tr>
<tr>
<td>Ni ubuhe buga buryo ukuresha ugiye kwa muganga?</td>
<td>[ ] na Bisi [ ] n’Imodoka [ ] n’amaguru [ ] Moto [ ] n’igare</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Iyo utitabiriye gahunda ya muganga, biba byatwe:</td>
<td>[ ] no kwibagirwa [ ] wahisemo/ utabashije kujiyayo [ ] Izindi mpamvu</td>
</tr>
</tbody>
</table>

Mu bibazo bikurikira turagusaba kuzuza ingingo zikurikira ku mpuzandengo kuva kuri 1( Simbyemera na gato) kugeza kuri 5( Ndabyemera cyane) ku bibazo 1-17. ICYITONDERWA: Nta gisubizo kizima cyangwa gipfuye kirimo.

<table>
<thead>
<tr>
<th>Simbyemera na gato</th>
<th>Simbyemera</th>
<th>ndifase</th>
<th>Ndabyemera</th>
<th>Ndabyemera cyane</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Muganga yansobanuriye indwara y’umutima iterwa na gapfura iyo ari yo.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Muganga wanjye yansobanuriye impamvu inshinge ari ngombwa.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Nizera ko iyi miti ifasha.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Mba nsabwa gufata iyi miti kabone nubwo naba numva nta bimenyetso byuburwayi mfite.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Kwiteza inshinge bingwa neza.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Abo mu rugo banyibutsa iteka kubahiriza gahunda ya muganga.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Nizera amakuru mpabwa nabaganga.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
8. Mba nshaka kujya kwa muganga ku gihe ariko nkabura imbaraga. | 1 | 2 | 3 | 4 | 5
9. Kuza hano kubonana na muganga binsaba igihe n’imbaraga. | 1 | 2 | 3 | 4 | 5
10. Icyo nshyira imbere kurusha ibindi ni ukubahiriza gahunda yo kubonana na muganga | 1 | 2 | 3 | 4 | 5
11. Gufata inshinge ntabwo bingwa neza. | 1 | 2 | 3 | 4 | 5
12. Gufata inshinge birababaza. | 1 | 2 | 3 | 4 | 5
13. Kuba inshinge zibabaza ubwabo bituma numva ntazifata. | 1 | 2 | 3 | 4 | 5
14. Urugendo rugera kwa muganga runca intege zo kwitabira gahunda za muganga. | 1 | 2 | 3 | 4 | 5
15. Iyo urebye ukuntu kuza kwa bihenze (kuza mu minsi yakazi, amafaranga yurugendo n’ibindi.) bituma ntashobora kuza. | 1 | 2 | 3 | 4 | 5
16. Amasaha yagenwe.yo kubonana na muganga biragoye kuyubahiriza | 1 | 2 | 3 | 4 | 5
17. Umwanya mara ntegereje kwa muganga nawo ushobora gutuma ntubahiriza gahunda ya muganga. | 1 | 2 | 3 | 4 | 5
APPENDIX 5.INFORMED CONSENT FORM-ENGLISH

Unique patient identifier number:

You are invited to participate in a research on” **Factors, beliefs and barriers associated with adherence to secondary prophylaxis amongst children with rheumatic heart disease at public tertiary hospitals of in Rwanda**”-a cross-sectional study.

Part I. Information sheet

1. **Purpose of the study**
We are about to carry out a study aiming at knowing how your child is receiving her/his monthly benzathine penicillin injections and what factors may prevent your child from not respecting the clinic appointments.

This will be a cross-sectional observational study of children diagnosed with rheumatic heart disease presenting to CHUK, CHUB, RMH, either to the outpatient or inpatient department.

2. **Description of the process**
The adherence to RHD secondary prophylaxis will be assessed by a self-reporting questionnaire where you will be asked to answer to some questions.

The data collection will go from the time of IRB approval till the sample size is attained. We will meet you in consultation room or hospitalization and the principle investigator or his representative will request you to answer some questions on a designed questionnaire.

The study will be approved by the Institutional Research Board of the CMHS and the CHUK, CHUB, RMH research and ethical committee.

3. **Risks or discomfort**
There are no anticipated risks associated with the participation in this study. However the research team will be open to discuss any discomfort and let the participant decide freely.

4. **Benefits**
You will not get any direct benefit but the information collected from the study may help to improve the adherence to secondary prophylaxis in patients with rheumatic heart diseases.
5. **Confidentiality**
Your identity and the information you will provide will be recorded under a study number and will not be disclosed or revealed.

6. **Voluntary participation, refusal or withdrawal**
Your participation is voluntary. It implies your consent. You may refuse to participate in the study or withdrawal from the study if you feel uncomfortable with the procedures used.

7. **For any questions about the study:**
Dr Janvier DUSHIMIRE (Principal Investigator): (+250) 788 859 271, e-mail: jdushimire@gmail.com

Dr Emmanuel K. RUSINGIZA (pediatric cardiologist, supervisor): (+250) 785 466 254, e-mail: erkamanzi@gmail.com

Prof. Kato N. NJUNWA (Chairperson, Institutional Review Board, CMHS, UR): (+250) 788490522

Prof. Jean Bosco GAHUTU (Deputy Chairperson, Institutional Review Board, CMHS, UR): (+250) 783 340 040

**Part II. Certificate of consent**
I have read the above information or it has been read to me. My questions have been answered. My signature below means that I do want to be in the study. I know that I can withdraw myself from the study at any time without any problems.

Name of participant:……………………….

Participant signature:……………………….

Date:………………/………………/…………..

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.

Name of witness:.................................................................

Thumb of participant:.........................................................

Signature of witness:............................................................

Date:..............................................................................

**Statement by the researcher/person taking consent**

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 persuaded into giving consent, and the consent has been given freely and voluntarily.

A copy of the informed consent form was given to the participant.

Name of the researcher/person obtaining consent:.............................................................................................

Signature:..............................................................................

Date:............................../................................./....................
APPENDIX 6.CHILD ASSENT FORM-ENGLISH

Patient identification number:

RESEARCH TOPIC:

“Factors, barriers and beliefs associated with adherence to secondary prophylaxis among children with rheumatic heart disease at public tertiary hospitals in Rwanda”–a cross-sectional observational study.

Doctor Janvier DUSHIMIRE, a 3rd year resident in Pediatrics, University of Rwanda, College of Medicine and Health sciences, phone number +250 788 859 271 and other doctors are carrying out a research study which will help them to know the rate of adherence to secondary prophylaxis among patients with rheumatic heart disease including me, this will help improve the care given to me and other patients by improving the adherence to secondary prophylaxis.

The doctor explained to me about the study she is conducting and will require my presence and response to some questions about how I respect my clinic appointments for benzathine penicillin injections. He will also use some recorded data in my file about my illness.

☐ I accept to participate in the study and respond to any question I will be asked to help Dr. Janvier DUSHIMIRE do his study.

☐ I authorize the use of some recorded data concerning my illness and use them in his research for public health purpose.

I have read and understood this notice and consent form. I voluntarily consent for myself and I have right to request and receive a copy of this form. A copy of this form will be as valid as the original.

Name and signature of the child……………………………………………………………………………………………………

Name and signature of the investigator…………………………………………………………………………………………

Signature of the parent or legal guardian…………………………………………………………………………………………

Date………………../………………../………………………


APPENDIX 7. CONSENT FORM-KINYARWANDA

INYANDIKO ISABA URUHARE KU BUSHAKASHATSI

Nimero iranga umurwayi:

Tubasabye ubufasha mu kugira uruhare ku bushakashatsi bufite insanganyamatsiko igira iti, “Imyumvire n’imbogamizi bijyanye no gutanga uburinzi bw’inyongera ku bana bafite indwara y’umutima ikomoka kuri gapfura mu bitaro bikuru byo mu Rwanda”

Igice cya 1: Urupapuro rusobanura igikorwa

1. Intego y’ubushakashatsi

Tugiye gukora ubushakashatsi bugamije kuminya uko umwana wanyu abona inshinge buri kwezi n’impamvu mutekereza zatuma atubahiriza gahunda ahabwa na muganga uko bikwiye.

Iyi ni inyigo ireba abana barwaye umutima mu bitaro bya CHUK, CHUK na RMH ku basezerewe n’abakiri mu bitaro.

2. Uko gahunda iteye

Kuminya uburyo hitabirwa kwivuza neza, tuzabimenya nyuma y’uko musubije ibibazo tubabajije.

Gukusanya aya makuru bizakorwa tumaze kubyemererwa aho tuzahura n’abarwayi aho basuzumirwa, aho barwarira ari naho tuzababariza ibibazo.

Ubu bushakashatsi buzemezwa n’akanama gashinzwe ubushakashatsi muri CMHS na CHUK.

3. Ibijyanye n’impungenge
Nta ngaruka duteganya ko zava mu kugira uruhare muri ubu bushakashatsi ariko ikipe ibukora izabaganiriza neza ku bishobora kubabangamira kugira ngo bifarire umwanzuro mu bwisanzure mu kubugirambo uruhare.

4. Inyungu

Ntabwo muzahita mubona inyungu zako kanya ariko amakuru azava mu bushakashatsi azabafasha kwivugurura mu buryo bwo kwivuza neza mu rwego rwo kwirinda indwara y’umutima ikomoka kuri gapfura.

5. Ibanga

Ibikuranga n’amakuru yawe bizagirwa ibanga.

6. Kugira uruhare k’ubushake


7. Ugize icyo ushaka kubaza

Dr Janvier DUSHIMIRE (umushakashatsi ): (+250) 788 859 271, e-mail: jdushimire@gmail.com
Dr Emmanuel K. RUSINGIZA (uvura indwara z’abana, supervisor): (+250) 785 466 254, e-mail: erkamanzi@gmail.com
Prof. Kato N. NJUNWA (Chairperson, Institutional Review Board, CMHS, UR): (+250) 788490522
Prof. Jean Bosco GAHUTU (Deputy Chairperson, Institutional Review Board, CMHS, UR): (+250) 783 340 040

Igice cya 2: Kwemeza ko ubyemeye

Izina ry’ukoreweho ubushakashatsi……………………………

Umukono……………………………………………………………

Itariki…………./…………./…………

**Niba atazi gusoma no kwandika**

Ntanze ubuhamyay ko nasomewe neza ubusobanuro bujyanye n’ubushakashatsi n’icyo bugamije kandi nkabona n’umwanya wo kubaza ibibazo kugira ngo nsobanukirwe kurushaho.

Mpamije ko mbyemeye nta gahato.

Amazina……………………………………

Igikumwe………………………………

Umukono……………………………………

Itariki…………./…………./…………

**Inyandiko y’umushakashatsi**

Ndemeza ko ukoreweho ubushakashatsi yahawe umwanya wo gusobanuza ibijyanye n’inyigo kandi ibibazo byabajije nabisubije mu buyo buboneye uko mbishoboye.

Ndanemeza ko uyu muntu atahatiriwe kwemera gutanga amakuru ahubwo yabyemeye ku bushake mu bwisanzure busesuye.

Fotokopi y’iyi nyandiko yahawe uwakoreweho ubushashakasti.

Izina ry’umushakashatsi

………………………………………………………………………………

Umukono………………………………………………………………

Itariki…………./…………./…………/………………
APPENDIX 8.ASSENT FORM-KINYARWANDA
IFISHI YUZUZWA N’ UMURWAYI:

Numero iranga umurwayi:

Insanganyamatsiko y’ubushakashatsi:

“Myyumvire n’imbogamizi bijyanye no gutanga uburinzi bw’inyongera ku bana bafite indwara y’umutima ikomoka kuri gapfura mu bitaro bikuru byo mu Rwanda”

Muganga Dushimire Janvier, umunyeshuri uminuza ibyo kuvura indwara z’abana muri Kaminuza y’u Rwanda muri Koleji y’Ubuvuzi N’ Ubumenyi mu by’Ubuzima, ufite nimoza za telefone 078859271 hamwe n’abandi baganga barimo gukora ubushakashatsi buzabafasha kumenya ibijyanye no kwivuza neza indwara y’umutima ikomoka kuri gapfura nanjye ndimo, bikazamfasha hamwe n’abandi barwayi kurushaho kwitabwaho hanozwu uburyo bwo kwivuza burinda iyi ndwara.

Muganga yansobanuriye neza ibijyanye n’ubushakashatsi arimo gukora, ansaba gusubiza ibibazo bijyanye n’uko nubahiriza gahunda zo kwiteza inshinge. Azakoresha amwe mu makuru yanjye ajyanye n’uburwayi nk’uko ari mu ifishi yanjye.

Nemeye gusubiza ibibazo bijyanye nabwo kugira ngo fashe muganga Dushimire Janvier kurangiza ubushakashatsi bwe.

Ntanze uruhushya rwo gukoresha amwe mu makuru ajyanye n’uburwayi bwanjye agakoresha mu bushakatsi bwe ku nyungu rusange z’ubuzima bw’abantu.

Nasomye kandi numva neza iyi fishi isaba amakuru kandi mbyemeye kubushake kandi mfite ubureganzira bwo gusaba no kubona fotokopi yayo ifite agaciro nka k’iyumwimerere.

Amazina n’umukono
by’umwana…………………………………………………………………………………………
Amazina n’umukono
by’umushakashatsi……………………………………………………………………………………………

Amazina n’umukono by’umubyeyi cyangwa urera umwana wemewe n’amategeko…………………………………………………………………………………………………………………………

Itariki…………………………/……………………/……………………………………………………………………
APPENDIX 9. UR-IRB CLEARENCE LETTER

Kigali, 12th/11/2018

Dr DUSHIMIRE Janvier  
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 377/CMHS IRB/2018

Your Project Title “Factors, Beliefs And Barriers Associated With Adherence To Secondary Prophylaxis Amongst Children And Adolescents With Rheumatic Heart Disease At Public Tertiary Hospitals In Rwanda – A Cross-Sectional Observational Study” Has been evaluated by CMHS Institutional Review Board.

<table>
<thead>
<tr>
<th>Name of Members</th>
<th>Institute</th>
<th>Involved in the decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof. Kato J. Njunwa</td>
<td>UR-CMHS</td>
<td>Yes</td>
</tr>
<tr>
<td>Prof Jean Bosco Gahutu</td>
<td>UR-CMHS</td>
<td>Absent</td>
</tr>
<tr>
<td>Dr Brenda Asiimwe-Kateera</td>
<td>UR-CMHS</td>
<td>Withdrawn from the proceeding</td>
</tr>
<tr>
<td>Prof. Ntanganira Joseph</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Dr Tumusiime K. David</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Dr Kayonga N. Egide</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Mr Kanyoni Maurice</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Prof Munyanshongore Cyprien</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Mrs Ruzindana Landrine</td>
<td>Kicukiro district</td>
<td>X</td>
</tr>
<tr>
<td>Dr Gishoma Darius</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Dr Donatilla Mukamana</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Prof. Kyamanywa Patrick</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Prof. Condo Umutesi Jeannine</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Dr Nyirazinyoye Laetitia</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Dr Nkeramihigo Emmanuel</td>
<td>UR-CMHS</td>
<td>X</td>
</tr>
<tr>
<td>Sr Maliboli Marie Josee</td>
<td>CHUK</td>
<td>X</td>
</tr>
<tr>
<td>Dr Mudenge Charles</td>
<td>Centre Psycho-Social</td>
<td>X</td>
</tr>
</tbody>
</table>

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 30th October 2018, Approval has been granted to your study.

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

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