# PREGNANCY RISK AND CONTRACEPTION AMONG REPRODUCTIVE AGE WOMEN WITH RHEUMATIC HEART DISEASE ATTENDING CARE AT JAKAYA KIKWETE CARDIAC INSTITUTE

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**By**

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**A Dissertation submitted in (Partial) Fulfillment of Requirements for the Degree of Master of Medicine in Internal Medicine of**

**Muhimbili University of Health and Allied Sciences**

**October, 2022**

## CERTIFICATION

The undersigned certifies that, He has read and hereby recommend for examination by Muhimbili University of Health and Allied Sciences a dissertation entitled: "**Pregnancy risk and contraception among reproductive age women with rheumatic heart disease attending care at Jakaya Kikwete Cardiac Institute"** in partial fulfilment of requirement for degree of Master of Medicine in Internal Medicine of Muhimbili University of Health and Allied Sciences.

_____

Dr. Reuben Mutagaywa (MD, MMED, MSc)

**(Supervisor)**

_____

Date

## DECLARATION AND COPYRIGHT

I, **David G. Paulo** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: …… Date: …….....

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My supervisor, Dr. Reuben Mutagaywa, thanks for the hard work you put into guiding this work until completion.

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My family, for your love and support in literally all aspects which made this journey worthwhile and endurable.

My fellow residents, you have been an awesome support system.

## DEDICATION

This work is dedicated to Philip- Promise, Hyasinta and my patients.

## ABSTRACT

**Background:** Rheumatic heart disease (RHD) remains prevalent in the developing part of the world and females including those of reproductive age are disproportionately affected. It is one of the commonest cardiac diseases during pregnancy and is associated with poor pregnancy outcomes. Despite its importance among reproductive age women, there are no local studies that focus in this patient population with respect to clinical characteristics, their risk of poor pregnancy outcomes as well as contraception which represents one effective way to prevent unwanted pregnancies in this patient population.

**Aim:** This study was aimed at describing the clinical characteristics, echocardiographic findings, pregnancy risk classification and contraception status among reproductive age women with RHD attending at the Jakaya Kikwete Cardiac Institute (JKCI).

**Materials and Methods:** This was a hospital based descriptive cross sectional study in which reproductive age women with echocardiographically diagnosed RHD were consecutively recruited from in- and out-patients' units of JKCI. A clinical research form was used to gather information on socio-demographic as well as clinical characteristics of patients and their contraception status. Information about echocardiographic findings (valvular lesions, ejection fraction, etc.) were recorded. The maternal/pregnancy risk class was determined using the modified World Health Organization (WHO) classification of maternal risk.

**Data handling and Analysis:** Data entry and analysis was done using SPSS for Windows version 23 (IBM SPSS, Chicago, IL). Data was presented as mean ± standard deviation/ median with range for continuous variables and percentages for categorical variables.

**Results:** A total of 238 females of reproductive age with an echocardiographic diagnosis of RHD were recruited from August, 2021 through January, 2022. The median age (range) of the participants was 36 years (15-49). Majority of the participants were of advanced maternal age (35-49) constituting more than half of the study population while those younger than 20 years comprised 14 (5.9%) of all participants. Almost two-thirds of participants resided outside Dar

es Salaam. Sixty-five percent were married and 102 (42.9%) had a secondary level of education. Thirty-five percent were unemployed and 159 (66.8%) were insured.

More than three quarters of the study participants were seen at the outpatient clinic and 18.1% were admitted. Seven (2.9%) participants had a history of stroke, one had diabetes mellitus and 6.7% had hypertension. The most commonly used medications were furosemide, spironolactone, ACEI/ARBs and warfarin. Almost two-thirds reported to be dyspneic on moderate exertion and on physical exam, 18.9% had lower limb edema. More than two-thirds were in NYHA class II and 17.2% were in NYHA class IV heart failure. Overweight and obese participants comprised 18.5% and 20.6% of all participants respectively. Almost a half of participants had a normal ECG while a quarter had atrial fibrillation/flutter.

The most common valvular lesion was MR followed by MS. Left atrial dilatation was present in more than a quarter, 17.2% had severely elevated pulmonary arterial pressures and 12.2% had reduced left ventricular ejection fraction.

Based on the modified WHO maternal risk classification system for women of reproductive age with heart disease, 66% of the participants were in class IV.

The proportion of contraception among reproductive age women with RHD was 7.1%. The commonest contraceptive method used was bilateral tubal ligation 5 out of 17 (29.4%), followed by implant (4 of 17). The most common reason for choice of a particular method was safety 10 out of 17 (58.8%).

**Conclusion:** Majority of reproductive age women with RHD are at the highest pregnancy risk based on the modified WHO classification and a very small proportion of them are on contraception. These results call for action among clinicians to offer counselling to these patients, educating them on their risk and offering appropriate contraception advice while waiting for definitive interventions.

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## LIST OF ABBREVIATIONS

| | | |
|---|---|---|
| AF | - | Atrial fibrillation |
| AR | - | Aortic regurgitation |
| ARF | - | Acute rheumatic fever |
| AS | - | Aortic stenosis |
| COCs | - | Combined oral contraceptives |
| ECG | - | Electrocardiogram |
| EF | - | Ejection fraction |
| ESC | - | European Society of Cardiology |
| HF | - | Heart failure |
| ICU | - | Intensive care unit |
| IUCD | - | Intrauterine contraceptive device |
| JKCI | - | Jakaya Kikwete Cardiac Institute |
| MR | - | Mitral regurgitation |
| MS | - | Mitral stenosis |
| MUHAS | - | Muhimbili University of Health and Allied Sciences |
| NYHA | | New York Heart Association |
| RHD | - | Rheumatic heart disease |
| TR | - | Tricuspid regurgitation |
| WHO | - | World health organization |

## DEFINITION OF KEY TERMS

**Rheumatic heart disease** is a disease affecting the heart valves following acute rheumatic fever (ARF) as a sequela to group A streptococcal pharyngitis(1).

**Pregnancy risk** in this study refers to the risk of adverse pregnancy outcomes due heart disease as per the modified WHO risk classification.

**Reproductive age women** refer to women in the age range of 15 to 49 years.

**Contraception** in this study is defined as the use of family planning methods like implants, contraceptive pills, barrier methods, injectable contraceptives, intrauterine devices, sterilization. Calendar method was not included in this study.

# CHAPTER ONE

## 1.0 INTRODUCTION

Rheumatic heart disease (RHD) is a disease affecting the heart valves following acute rheumatic fever (ARF) as a sequela to group A streptococcal pharyngitis(1). Rheumatic heart disease commonly affects children and adolescents mostly in the developing regions of the world. While rheumatic heart disease is currently rare in the developed world, low and middle income countries are still heavily affected(2). Females are more commonly affected by RHD than males. In most hospital as well as community based studies, females contribute almost two- thirds of all patients with RHD(2,3).

RHD is common in pregnancy contributing up to 30% of heart diseases during pregnancy(4) and it associated with poor pregnancy outcomes(5). This is because pregnancy is characterised by physiological changes including a relative increase in effective circulating volume, an increase in heart rate, decreased peripheral vascular resistance and apparent anemia due to dilution(6–9). It is generally a high output state. These changes are well tolerated by women without preexisting heart disease. On the other hand, women with heart disease including RHD are at a higher risk of heart failure and poor pregnancy outcome.

The 2018 European Society of Cardiology (ESC) guidelines on the management of cardiovascular diseases during pregnancy recommend performing risk assessment in all women of childbearing age with cardiac diseases using the modified WHO classification of maternal risk(10). In this modified WHO risk classification, there are five classes of cardiac diagnoses: I, II, II-III, III and IV. Diagnoses included in class IV include: pulmonary arterial hypertension, severe mitral stenosis, severe symptomatic aortic stenosis, severe left ventricular systolic dysfunction (ejection fraction less than 30%) among others. The higher the class, the more the risk of complications. Pregnancy is contraindicated in patients who fall in class IV. Hence counselling is recommended in all women of reproductive age with heart disease

including RHD prior to conception including offering contraception to prevent unwanted pregnancies.

## 1.1 LITERATURE REVIEW

It is estimated that ARF and subsequent RHD affects about 15.6 million people worldwide(11). Current WHO estimates of annual deaths from RHD are at around 291,000. The burden of RHD globally varies between countries depending on the level of development. The prevalence is low in developed countries and higher among low and middle income countries(12). A retrospective study from Queensland, Australia which reviewed data from 1997 to 2017 found a prevalence of 12/1000 in the indigenous population and 2/1000 in the non-indigenous population, highlighting socio-economic status as a major determinant of RHD prevalence. This study also found an increase in incidence of RHD from 4.7/1,000,000/year in 1997 to 49.4/1,000,000/year in 2017(13). A systematic review in India estimated the prevalence of RHD among children aged 5-15 years to be 0.5/1000 though different studies had variable results depending on the population and methods used(14).

Sub- Saharan Africa (SSA) is one of the hotspots of RHD with an estimated prevalence of 5.7 per 1000 in children aged 5-14 years(11).. The heart of Soweto study found an incidence of RHD of 23.5 cases per 100,000 per annum among those aged above 14 years in urban South Africa(15). In a study that involved screening of more than a thousand school children in 15 schools in Zambia, the prevalence of definite RHD was 2.7 per 1000(16). In Cameroon, a hospital based cross-sectional study that involved reviewing echocardiograms performed over a 1 year period found a prevalence of definite RHD as per World Heart Federation criteria to be 3.1%(17). A retrospective study from Nigeria which reviewed echocardiographic data over 48 months found a prevalence of RHD of 9.8%(18). Another cross- sectional study from Lagos, Nigeria found a prevalence of RHD among children with structural heart diseases of 2.6% translating to a 1.1/10,000 prevalence among children admitted at the study hospital(19). A cross-sectional study from Rwanda that involved echocardiographic screening of 2501 school children found a 6.8/1000 prevalence of definite RHD(20). A study with similar

methodology conducted among school children in Senegal came up with an RHD prevalence of 4.96/1000(21)

In Tanzania, RHD was a contributor of 12% of heart failure (HF) cases among adults aged above 18 years(22). A 2017 meta-analysis of data from Uganda and Tanzania found a combined prevalence of RHD of 17.9 per 1000 among school age children(23).

The female gender is disproportionately affected by RHD compared to males. The REMEDY study, a prospective cohort study which enrolled more than 3300 people from 12 countries in Africa, India and Yemen found a female proportion of 66.2% majority of whom were in the reproductive age range(2). In this study, 86.5% of women in low-income and 90.1% in lower-middle-income countries were in the reproductive age range. In a prospective observational study on clinical characteristics of patients with RHD conducted at a tertiary hospital in Myanmar, 70% of participants were female and majority of them were in reproductive age(24). These findings are not far away from local findings in Tanzania where, among people with echocardiographically diagnosed RHD, females were the majority at 61.7%(3). However, there are no local studies that have focused primarily on reproductive age women with RHD.

RHD is associated with poor pregnancy outcomes in women who concieve before correction of the valvular diseases. In a retrospective study that included 50 women with RHD in Dakar, Senegal over a period of 8 years, maternal mortality approached 34%(5). In a 3 year prospective observational study in Egypt, RHD among pregnant women was associated with poor maternal and fetal outcomes including heart failure, sustained arrhythmias, thromboembolism, admission to cardiac ICU, delivery by ceasarian section, postpartum hemorrhage and maternal death. In this study, maternal death was 5% among women with RHD and advanced heart failure (NYHA III and IV)(25). In a large retrospective study done in China with data from 2010 to 2017 looking into pregnancy outcomes among women with heart disease, the proportion of the study participants who had RHD was 22.5% and it had a major contribution to maternal cardiac complications. In this study maternal cardiac complications occured more commonly among those who had RHD (32.9%) and these

complications included severe arrhythmias, venous thromboembolism, heart failure among others(26). The pregnancy risk of reproductive age women with RHD is unknown locally.

Prevention of unwanted pregnancies through effective contraception prior to definitive treatment of valvular lesions due to RHD is a possible solution to prevent poor pregnancy outcomes.

In the general population, uptake of contraception is variable. Worldwide, the proportion of adolescent women on contraception is estimated to be 10.2%(27). A large cross-sectional study that included data from more than 1 million reproductive age women in twenty African countries found an overall prevalence of contraception of 26% with the highest in Zimbambwe (62%) and the lowest in Guinea with a prevalence of 6%(28). A cross-sectional study done in Juba, South Sudan revealed a prevalence of contraception of 42.6% among women of reproductive age(29). Trends in some African countries have shown a slow increase in upatake of contraception over many years as shown by a study in Zambia that analysed data between 1996 and 2014. This study found prevalence of contraception of 7.6% and 10.9% respectively in the two years(30). In Mali, the prevalence of modern contraception use was 17.1% among adolescent girls and young women(31).

However, it has been shown that there is suboptimal contraception among reproductive age women with RHD in the developing world(2). In a large study of patients with RHD involving 12 countries in Africa, the middle East and India, the proportion of contraception among reproductive age women with RHD was 3.6%(2). The proportion of reproductive age women with RHD on contraception is not known in Tanzania.

The European society of cardiology recommends classifying women of reproductive age with heart diseases including RHD according to the modified WHO pregnancy risk classification and offering preconception counselling.

## 1.2 PROBLEM STATEMENT

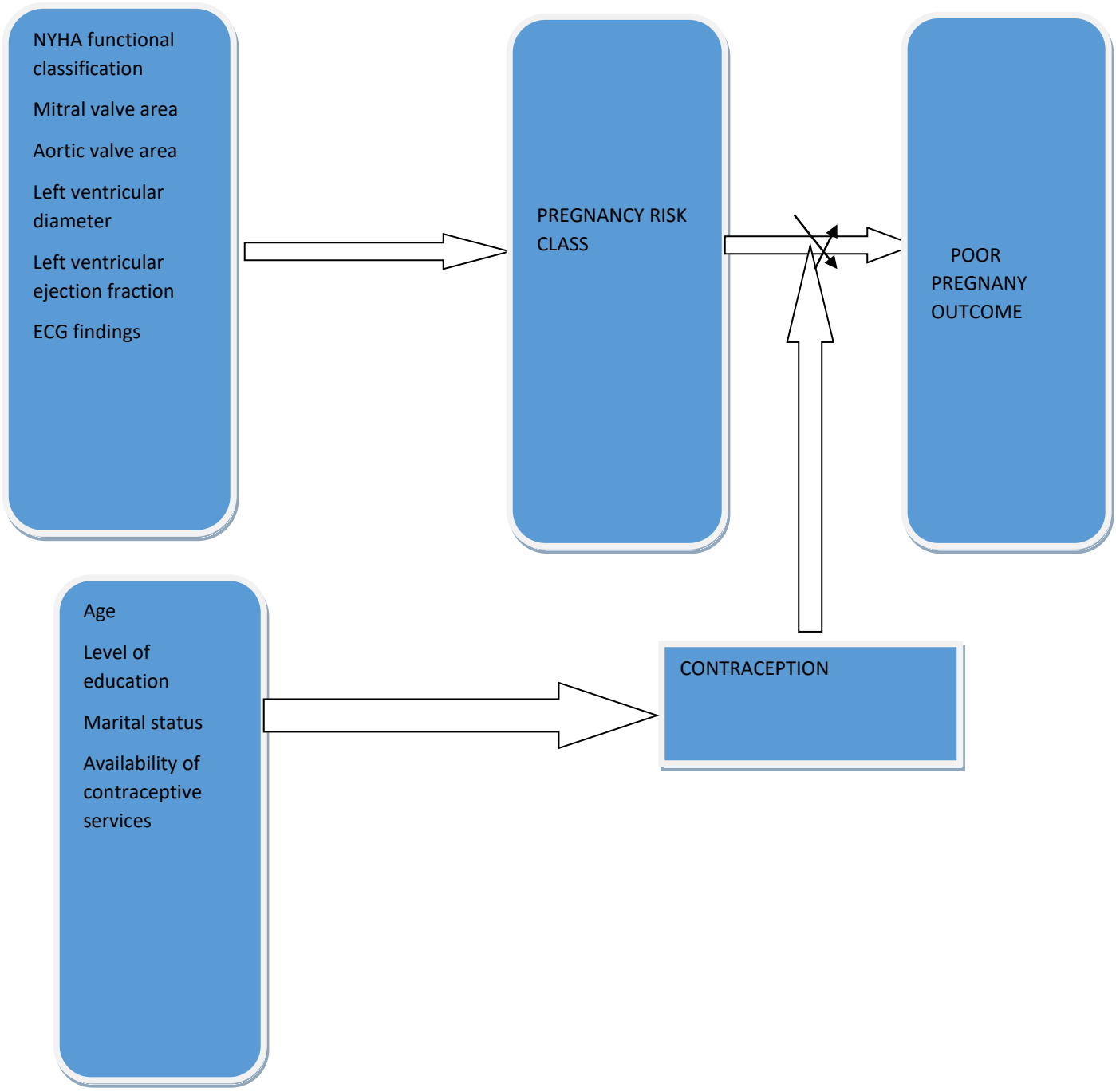
Rheumatic heart disease affects women of reproductive age and carries a risk of poor pregnancy outcomes both to the mother and fetus. Determining the pregnancy risk in reproductive age women is crucial in order to offer appropriate counselling with regards to conception.

There is no published data locally on the pregnancy risk classification of reproductive age women with RHD.

Also, the proportion of reproductive age women with RHD who are on contraception is not known in our setting.

Also, studies have revealed gender based differences in patterns of RHD lesions. There are no local studies focused on characterization of RHD in women of reproductive age.

## 1.3 CONCEPTUAL FRAMEWORK



## 1.4 RATIONALE OF THE STUDY

Despite the magnitude of RHD among women of reproductive age, there are no studies in our setting that have described the clinical and imaging findings of this group of patients in terms of WHO risk classification in order to determine the need for specific counselling with regards to pursuing pregnancy and the associated risk and the need for contraception. The absence of systematically collected data is a gap that needs to be urgently bridged, as an initial step in reducing maternal morbidity and mortality among women with RHD.

A significant proportion of adverse pregnancy outcomes contributed to by RHD can be prevented by avoiding unwanted pregnancies through effective contraception. However, a number of studies in Africa have shown suboptimal levels of contraception among reproductive age women with RHD.

There are no local studies on contraception among reproductive age women with RHD.

Reliable data on pregnancy risk and contraception among reproductive age women with RHD will help clinicians to come up with strategies to improve patient care and ensure better pregnancy outcomes. The coming data may be instrumental in influencing development of local guidelines on management of reproductive age women with RHD.

This study aims to collect data on the clinical characteristics, echocardiographic findings, pregnancy risk and contraception among reproductive age women with RHD in our setting where RHD is highly prevalent.

## 1.5 RESEARCH QUESTIONS

Overall research question

What is the pregnancy risk classification and contraception status among reproductive age women with rheumatic heart disease attending the Jakaya Kikwete Cardiac Institute?

**Specific research questions**

1. What are the clinical characteristics of reproductive age women with rheumatic heart disease?
2. What are the Echocardiographic findings among reproductive age women with RHD?
3. What is the pregnancy risk among reproductive age women with RHD?
4. What is the proportion of contraception among reproductive age women with RHD?

## 1.6 STUDY HYPOTHESIS

The pregnancy risk among reproductive age women with RHD is high and the proportion of reproductive age women with RHD on contraception is low.

## 1.7 OBJECTIVES

### 1.7.1 Broad objective

To determine the pregnancy risk and proportion of contraception among reproductive age women with RHD attending JKCI.

### 1.7.2 Specific objectives

1. To describe the clinical characteristics of reproductive age women with RHD attending JKCI.
2. To describe echocardiographic findings of reproductive age women with RHD attending JKCI.
3. To determine the WHO pregnancy risk classification of reproductive age women with RHD attending JKCI.
4. To determine the proportion of reproductive age women with RHD on contraception.

# CHAPTER TWO

## 2.0 METHODOLOGY

### 2.1Study design

Hospital based descriptive cross-sectional study

### 2.2 Study area

In the Cardiac wards and outpatient clinics at JKCI. JKCI is a national tertiary level hospital which receives patients from all regions of United Republic of Tanzania referred by regional and zonal referral hospitals for cardiovascular diseases treatment, both medical and surgical. It has capacity of 103 beds serving about 800 patients per week.

### 2.3 Study population

Reproductive age women with echocardiographically diagnosed RHD**.**

### 2.4 Study duration

Six months (August 2021 to January, 2022)

### 2.5 Inclusion criteria

Women aged between 15 and 49 with an echocardiographic diagnosis of RHD

### 2.6 Exclusion criteria

None

### 2.7 Sample size

The sample size was calculated by using the following formula,

$Nr = Z^2 p\ (1-p)/e2$

Where

Nr = sample size

Z = standard normal deviation of 1.96 corresponding to 95% confidence interval

P = proportion of reproductive age women with RHD on contraception was found to be 19% in a study including reproductive age women with RHD in Myanmar(24).

e = 5%

$Nr = (1.96)^2 \times 19(100 - 19)/ (5)^2$

Nr = 237.

**2.8 Sampling Method**

The sampling frame included all reproductive age women attending cardiac clinic and those who are admitted in cardiac wards at JKCI. A consecutive sampling method was used to obtain the required sample size.

The investigator visited the cardiac wards, cardiac clinics and the echocardiography room on a daily basis to look for reproductive age women with an echocardiographic diagnosis of RHD. Once these were identified, they were informed and asked to participate in the study.

**2.9 Variables**

**Continuous variables** included age, ejection fraction

**Categorical variables** included age groups, marital status, education level, severity of valvular disease, WHO pregnancy risk class, heart failure status, heart failure class, and contraception status.

**2.10 Data collection**

The investigator, on a daily basis visited the cardiac wards to look for any reproductive age woman with a diagnosis of RHD**.** The investigator also visited the cardiac clinics which are run daily and requested to interview any woman with an echocardiograpic diagnosis of RHD for possible inclusion in the study. Consecutive patients with RHD as per echocardiographic diagnosis were then recruited in the study.

A clinical research form was used for collecting information on demographic characteristics including age, occupation as well as area of residence. Also clinical characteristics of the patients were recorded which included symptoms like dyspnea on exertion, cough, orthopnoea , etc.

All patients underwent physical examination and the findings of Jugular Venous Pressure, edema, lung crepitations, etc were recorded. Framingham criteria were used to make a clinical diagnosis of heart failure among these women of reproductive age with RHD. Patients were then classified to New York Heart Association (NYHA) classes I – IV according to their symptoms.

Echocardiography results were reviewed to record the kinds of valvular lesions and their severity in terms of valve area, the left ventricular ejection fraction and pulmonary pressures. These results were used to classify women based on the modified WHO pregnancy classification among women with heart disease.

Patients were also asked whether they are currently on any method of contraception or not and if yes the type of contraception.

**2.11 Demographic and clinical data**

A clinical research form was used to collect information on demographic characteristics including age, employment status as well as area of residence. Also used to collect information on medical history including hypertension, diabetes mellitus, cigarette smoking, and alcohol consumption. Clinical characteristics of the patients were recorded which includes symptoms like dyspnea on exertion, cough, orthopnea, paroxysmal nocturnal dyspnea, etc.

All patients underwent physical examination and the findings of heart rate, rhythm, Jugular Venous Pressure, edema, ascites, lung crepitations, etc. were recorded. Medications used by the patients were recorded. Blood pressure was taken using an automated digital sphygmomanometer with the patient in supine position. The average of two readings taken at least 5 minutes apart was recorded as the patient’s blood pressure. Patient’s body weight (in kg) was taken using a well-calibrated weighing scale, with patient wearing no shoes or heavy

clothing. Height (in cm) was taken using a stadiometer and recorded to the nearest centimeter. Height and weight were used to calculate body mass index (BMI) using the formula: height (kg)/weight ($m^2$). And classified into underweight, normal BMI and Obesity was defined as BMI $\geq$30kg/$m^{2.}$

Electrocardiograms were also obtained. A 12-lead resting electrocardiogram was obtained from all patients. A Bionet Cardio 7 machine was used. Reading of the ECGs was done manually, coding and interpretation was done using the Minnesota coding system. All ECGs were read by the primary investigator in agreement with a cardiologist performing echocardiography and then proof-read by the supervisor.

**2.12 Echocardiography**

The echocardiogram examinations followed the American Society of Echocardiography guidelines. A cardiologist and investigator or investigator under a senior cardiologist supervision did all echocardiograms then a supervisor cardiologist reviewed the findings. Different echocardiographic parameters were defined based on the American Society of Echocardiography guidelines.

**2.13 Pregnancy risk**

The collected clinical and echocardiographic data were used to classify the pregnancy risk of reproductive age women with RHD using the modified WHO pregnancy risk classification system.

**2.14 Contraception**

Using a structured questionnaire, participants were asked if they were currently on any method of contraception and if yes what type of contraception and the reasons for their choice of the specific type of contraception. This information was recorded.

### 2.15 Data entry and analysis

The collected data was checked for quality and coding was done prior to entering into the computer statistical program. Data was analyzed using SPSS for Windows version 23. Data was presented as mean ±SD/ median with range for continuous variables and as percentages for categorical variables.

### 2.16 Ethical clearance

The study was done in accordance with the Helsinki Declaration of research on Human subjects. Ethical clearance to conduct the study was obtained from Muhimbili University of Health and Allied Sciences' Ethical Review Board. Permission to do the study was obtained from JKCI management.

Informed consent was obtained from all study participants before they were enrolled in the study. Patients eligible to participate in the study were included only after being provided with Informed consent (annex I) following the process as outlined below:

1. The patients were informed that the project involves local research
2. They were told about the purpose of the study
3. The procedures of the study were explained clearly with full details of all the tests to be done
4. They were assured that participation is voluntary and that no medical attention will be denied if they declined to participate
5. The participants were informed of the medical benefits and also physical and psychological harms to their satisfaction prior to being included in this study
6. The subjects were assured of full and free access to their results and that the therapeutic interventions will be recommended where the need arises, according to accepted standard of practice
7. They were asserted that confidentiality will be strictly maintained and all data will be securely stored

For those younger than 18 years of age, both the participant and guardian/ caretaker were informed and thereafter, permission to participate was obtained and the guardian signed the consent forms.

**2.17 Disposal of Study results**

All findings (physical and investigations) were communicated to the patients by the investigator. All findings were discussed with doctors managing the patients. The care of the patient both in-patient and out-patient continued as per hospital recommendations.

# CHAPTER THREE

## 3.0 RESULTS

### 3.1 Baseline characteristics of the study population

A total of 238 females of reproductive age with an echocardiographic diagnosis of RHD were recruited during the study period. No patient was excluded. The median age (range) of the participants was 36 years (15-49). Majority of the participants were of advanced maternal age (35-49) constituting more than half of the study population while those younger than 20 years comprised 5.9% of all participants. Almost two-thirds of participants resided outside Dar es Salaam. Sixty-five percent were married and 42.9% had a secondary level of eduction. Thirty-five percent were unemployed and 66.8% were insured.

**TABLE 1: SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS**

| **CHARACTERISTIC** | **FREQUENCY (%) N=238** |
|---|---|
| **AGE** | |
| MEDIAN (RANGE) | 36 (15-49) |
| AGE GROUP | |
| 15- 19 | 14 (5.9) |
| 20- 34 | 90 (37.8) |
| 35- 49 | 134 (56.3) |
| **RESIDENCE** | |
| Dar es Salaam | 94 (39.5) |
| Other regions | 144 (60.5) |
| **MARITAL STATUS** | |

| | |
|---|---|
| Married | 155 (65.1) |
| Single | 74 (31.1) |
| Widowed/ Separated | 9 (3.8) |
| **EDUCATION LEVEL** | |
| No formal education | 2 (0.8) |
| Primary | 91 (38.2) |
| Secondary | 102 (42.9) |
| College/ university | 43 (18.1) |
| **OCCUPATION** | |
| Employed | 77 (32.4) |
| Self employed | 76 (31.9) |
| Unemployed | 85 (35.7) |
| **SOURCE OF FUNDING** | |
| Insurance | 159 (66.8) |
| Out of pocket | 79 (33.2) |

### 3.2 Clinical characteristics of participants

More than three quarters of the study participants were seen at the outpatient clinic and 18.1% were admitted. Seven participants had a history of stroke, one had diabetes mellitus and 6.7% had hypertension. The most commonly used medications in descending order were furosemide, spironolactone, ACEI/ARBs and warfarin. Almost two-thirds reported to be dyspneic on moderate exertion and on physical exam, 18.9% had lower limb edema. More

than two-thirds were in NYHA class II and 17.2% were in class IV heart failure. Overweight and obese participants comprised 18.5% and 20.6% of all participants respectively. Almost a half of participants had a normal ECG while a quarter had atrial fibrillation/flutter.

**TABLE 2: CLINICAL CHARACTERISITICS OF PARTICIPANTS, N=238**

| **CHARACTERISTIC** | **FREQUENCY (%)** |
|---|---|
| **VISIT TYPE** | |
| Outpatient | 195 (81.9) |
| Inpatient | 43 (18.1) |
| **MEDICAL HISTORY*** | |
| Hypertension | 16 (6.7) |
| Diabetes mellitus | 1 (0.4) |
| Stroke | 7 (2.9) |
| **DRUG HISTORY*** | |
| ACEI/ARB | 127 (53.4) |
| Warfarin | 105 (44.1) |
| CCB | 2 (0.8) |
| Beta blocker | 52 (28.1) |
| Furosemide | 187 (78.6) |
| Spironolactone | 164 (68.9) |
| Digoxin | 14 (5.9) |
| **SYMPTOMS*** | |

| | |
|---|---|
| Dyspnea | 150 (63.0) |
| Nocturnal cough | 55 (23.1) |
| Paroxysmal nocturnal dyspnea | 59 (24.8) |
| **PHYSICAL EXAM FINDINGS*** | |
| Ankle edema | 45 (18.9) |
| Tachycardia | 82 (34.5) |
| Irregular rhythm | 63 (26.5) |
| High blood pressure | 10 (4.2) |
| Elevated JVP | 30 (12.6) |
| Displaced apex | 38 (16.0) |
| Basal crackles | 30 (12.6) |
| **NYHA CLASS** | |
| II | 161 (67.6) |
| III | 36 (15.1) |
| IV | 41 (17.2) |
| **BMI CATEGORY** | |
| Underweight | 25 (10.5) |
| Normal | 120 (50.4) |
| Overweight | 44 (18.5) |
| Obesity | 49 (20.6) |

| **ECG FINDING** | |
|---|---|
| NORMAL ECG | 101 (42.4) |
| SINUS TACHYCARDIA | 44 (18.4) |
| ATRIAL ENLARGEMENT | 19 (8) |
| ATRIAL FIBRILLATION/ FLUTTER | 64 (26.9) |
| LEFT VENTRICULAR HYPERTROPHY | 7 (2.9) |
| FIRST DEGREE HEART BLOCK | 3 (1.2) |

*percent do not add to 100%

### 3.3 Echocardiographic findings

The commonest valvular lesion was MR followed by MS. Left atrial dilatation was present in more than a quarter, 17.2% had severely elevated pulmonary arterial pressures and 12.2% had reduced left ventricular ejection fraction.

**TABLE 3: ECHOCARDIOGRAPHIC FINDINGS OF PARTICIPANTS**

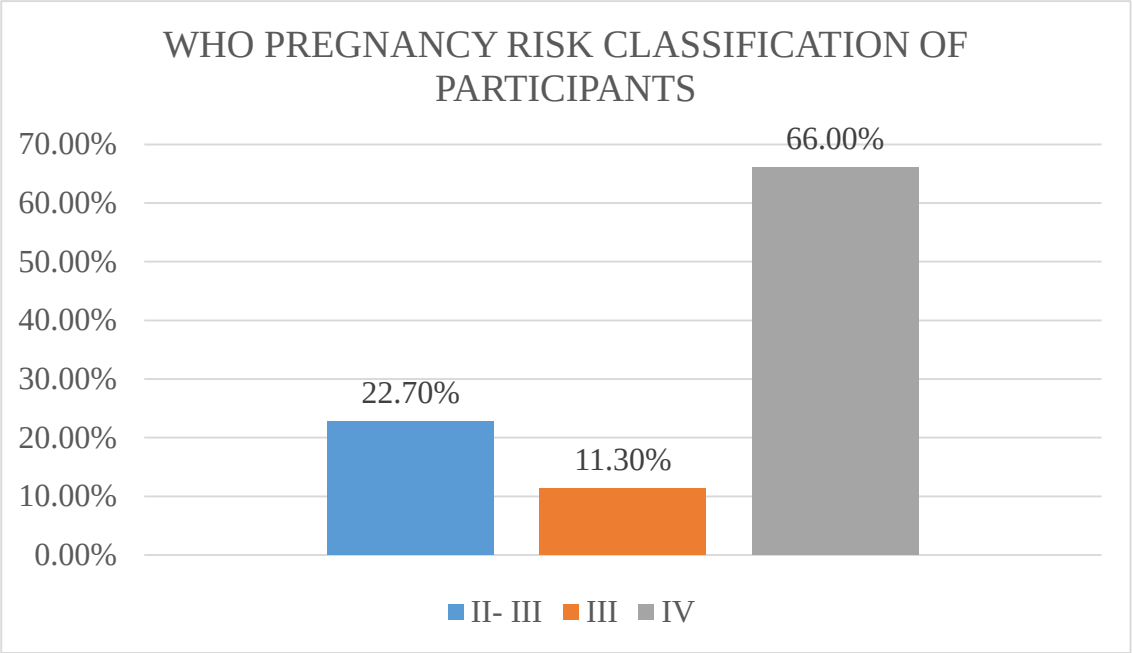
| **ECHO FINDING** | **FREQUENCY (%)** |
|---|---|
| **VALVULAR LESIONS** | |
| Mitral regurgitation | 162 (68.1) |
| Mitral stenosis | 159 (66.8) |
| Aortic regurgitation | 88 (37) |
| Aortic stenosis | 14 (5.9) |
| Tricuspid regurgitation | 103 (43.3) |
| **CARDIAC CHAMBERS** | |

| | |
|---|---|
| Left ventricular hypertrophy | 10 (4.2) |
| Left ventricular dilation | 57 (23.9) |
| Right ventricular dilatation | 19 (8.0) |
| Left atrial dilatation | 186 (78.2) |
| Right atrial dilatation | 79 (33.2) |
| **RIGHT VENTRICULAR SYSTOLIC PRESSURE** | |
| Normal | 176 (73.9) |
| Mildly elevated | 12 (5.0) |
| Moderately elevated | 9 (3.8) |
| Severely elevated | 41 (17.2) |
| **LEFT VENTRICULAR EJECTION FRACTION** | |
| Normal | 174 (73.1) |
| Mildly reduced | 35 (14.7) |
| Reduced | 29 (12.2) |

### 3.4 Pregnancy risk classification of participants

Based on the modified WHO maternal risk classification system for women of reproductive age with heart disease, 66% of the participants were in class IV.

**FIGURE 1: PREGNANCY RISK CATEGORY OF PARTICIPANTS**




### 3.5 Contraception among participants

The proportion of contraception among reproductive age women with RHD was 7.1%. The commonest contraceptive method used was bilateral tubal ligation (29.4%), followed by implant (4 of 17). The most common reason for choice of a particular method was safety (58.8%).

**TABLE 4: METHODS OF CONTRACEPTION USED BY PARTICIPANTS, N=17**

| METHOD | FREQUENCY (%) N=17 |
|---|---|
| Implant | 4 (23.5) |
| IUCD | 3 (17.7) |
| COCs | 2 (11.8) |
| Barrier method | 1 (5.9) |
| Injection | 2 (11.8) |
| Bilateral tubal ligation | 5 (29.4) |

**TABLE 5: REASONS FOR CHOICE OF CONTRACEPTIVE METHOD**

| REASON | FREQUENCY (%) N=17 |
|---|---|
| Safe | 10 (58.8) |
| Easy | 4 (23.5) |
| Reversible | 2 (11.8) |
| Advised by health care worker | 1 (5.9) |

# CHAPTER FOUR

## 4.0 DISCUSSION

This study found out that a large proportion (66%) of reproductive age women with RHD are at the highest risk (class IV) of poor pregnancy outcomes based on the modified WHO pregnancy risk classification system. The study also found out that the proportion of these women on contraception is low. Reproductive age women with heart disease including RHD are at an increased risk of poor pregnancy outcomes both maternal and fetal. These include maternal death, now onset arrhythmias, hospitalization for heart failure, cardiac intervention and thromboembolic events(32). Fetal outcomes include intrauterine fetal death, intrauterine growth restriction, preterm birth and low birth weight among others(33). Hence, proper pre-conception counselling should be offered to inform them on their risk and offering contraception to prevent unwanted pregnancies. There are no locally available studies conducted to inform on the pregnancy risk of reproductive age women with RHD and contraception in this patient population. This study was set out to fill that gap.

This is the first local study to report maternal risk among reproductive age women with RHD. There are no local and regional studies that have categorized reproductive age women with RHD based on this risk classification system and hence this study serves as an eye opener that most women with RHD carry the highest maternal risk. Approximately two-thirds of the study participants had the highest maternal risk (class IV) based on the modified WHO maternal risk classification system. The clinical and echocardiographic findings contributing to this high risk include severe MS, severe symptomatic aortic stenosis (AS), class III or IV heart failure and a reduced ejection fraction <30%. This represents a patient population in whom pregnancy is contraindicated and if they present pregnant, termination should be considered. Class IV WHO risk category was also found to be the most predominant in a study conducted among 80 pregnant women with native valve RHD or after valve intervention. In this study, 36.2% pregnant women had modified WHO risk score class IV(32). The differences in the proportions between the two studies are due to the fact that, in the Indian study, majority of the

women (63.7%) had undergone prior intervention either balloon valvotomy or valve replacement which downgrades the risk from class IV to III.

The most common presenting symptom in this study was dyspnea on ordinary exertion which was reported by 63.0% of the study participants consistent with findings from other studies(34). This is lower than that reported by Ruggajo in a 2008/2009 study conducted at MNH where he recruited all patients referred for echocardiography and further studies those found to have RHD. In his study, the prevalence of dyspnea on ordinary exertion was 82.7%(3). The differences in this finding can be explained by the fact that in the current study, the patients were already attending care at JKCI which is a tertiary cardiac center in the country and hence majority were already on heart failure medications. Dyspnea on exertion was also found to be the commonest presenting symptom in patients with RHD in a study done in Myanmar accounting for 91% of all symptoms(24). This proportion is higher than that found in the current study and this is because in the Myanmar study, the patients with RHD were all recruited from admitted patients reflecting more severe disease and decompensation.

In this study, participants with heart failure NYHA class III and IV were 15.1% and 17.2% respectively making a total of 32.3% which is comparable with 29.1%among adults with RHD in the lower-middle income countries subgroup found in the REMEDY study(2). Patients with NYHA class IV in the index study compare very closely with the proportion of patients who were admitted, which was 18.1%. The study in Myanmar had a higher proportion of patients with NYHA class III or IV heart failure (57%)(24). The patients in this study were admitted patients indicating more severe heart failure symptoms hence explaining the higher proportion of higher classes of heart failure. Previous studies have shown that NYHA class III and IV heart failure was associated with higher morbidity and mortality among reproductive age women with RHD.

On echocardiography, the most common valvular lesion found in this study was mitral regurgitation (MR) constituting 68.1% followed by mitral stenosis (MS) (66.8%), a finding consistent with that from a study done in Ethiopia(35). The mitral valve was also the most commonly involved valve in the Myanmar study(24). The study by Ruggajo(3) had a similar

finding with MR being the most common valvular lesion but with a higher proportion (84.0%) followed by tricuspid regurgitation (TR) (31.3%) then MS (24.7%). In the current study, the prevalence of TR was 43.3% making it the third most common valvular lesion. The observed differences could be due to the fact that Ruggajo recruited all patients referred for echocardiography while the current study involved reproductive age women who were already echocardiographically diagnosed to have RHD and hence they were attending follow up clinics including in preparation for various interventions and hence this represents a highly selected patient population. Mitral regurgitation has been found to be the commonest lesion in multiple other studies(34,36–39). Left atrial dilatation was the commonest chamber abnormality present in 78.2% of participants. This finding is consistent with that from the study in Myanmar in which the prevalence of left atrial dilatation was 82%(24). The prevalence of left ventricular dilatation was 23.9% a finding similar to that in the REMEDY study which was 23%(2). About three quarters of participants in this study had normal pulmonary arterial pressures and 17.2% had severely elevated ones implying severe pulmonary hypertension. In his study, Ruggajo found the prevalence of severe pulmonary hypertension to be 12%. Again, this small difference between the two studies from the same setting but separated in time can be because in the study by Ruggajo, the patients had been referred for echocardiography after they presented to health facilities with symptoms representing early disease for most while in the current study, some patients have been having RHD for a long time hence representing advanced disease with complications including pulmonary hypertension.

About a fourth of patients in this study had either mildly reduced (41-49%) or reduced (<40%) ejection fraction (EF) with 12.2% having a reduced EF. This represents a patient population that is highly symptomatic and which will require hospital admission due to decompensation and this proportion closely corresponds with the proportion of admitted patients (18.1%) and those with NYHA class IV heart failure (17.2%). In the REMEDY study, the prevalence of decreased EF among adults was 18.3%(2).

The prevalence of atrial fibrillation (AF) by ECG was found to be 26.9% which is slightly higher than the 21.9% which was found in the REMEDY study. These differences can be explained by the diversity of the study population in the REMEDY study which included both young and old patients as well as male and female patients and was conducted in 14 different countries, 12 being in Africa and the other two being Yemen and India. The study population was younger in the REMEDY study with a median age of 28 compared to this study with a median age of 36. Several studies have shown that the prevalence of AF in patients with RHD varies depending on age(40,41),left atrial diameter(42,43) and duration of disease. The prevalence from both studies is lower than the global prevalence of AF in RHD which is 32.8% (41). The study by Ruggajo conducted at MNH found a prevalence of atrial fibrillation of only 9.3% among patients with RHD. This was based on physical examination. This underscores the fact that the sensitivity of physical examination is low and hence ECG supplements the physical findings. The Myanmar study(24) found a higher prevalence of atrial fibrillation of 63%. This was a small study with a sample size of 96 patients and all patients were admitted. An Ethiopian study which recruited admitted patients found a prevalence of AF of 48.9%(35). These findings further add to evidence that more severe disease is associated with a higher prevalence of atrial fibrillation(41). A study done in Uganda had an AF prevalence of 20.3% at baseline and 64% at one year(44).

Despite the observed high maternal risk in this study, the proportion of reproductive age women with RHD who were on contraception in this study were only 7.1%. The REMEDY study found an even lower proportion of contraception at 3.6% among women aged 12-51 years(2). A study conducted in Myanmar found that in the same population of reproductive age women with RHD, the proportion of contraception was 19%(24). Overall, very few studies have investigated contraception among reproductive age women with RHD. Cardiology authorities, both regional(45) and global(10) advocate counselling to these patients including offering contraception. In the current study, almost half of all participants were told by their attending doctor that they were not strong enough to be pregnant but they were not specifically told to be on contraception. A study done in New Zealand found that contraception was discussed with only 38% of patients with heart disease and it was less likely

to be discussed with RHD patients(46). The reasons could be a high workload leading to shortage of time to discuss contraception options, lack of contraception expertise among clinicians attending these patients and cultural issues.

The most common method of contraception was bilateral tubal ligation used by 5 of the 17 participants who were on contraception followed by implant used by 4 participants. An intrauterine device was used by 3 participants. In this patient population, the type of contraceptive method used is also important both in terms of efficacy and safety. One participant was using barrier method. Even in very reliable hands, the failure rate of this method is high and hence for a reproductive age woman with high maternal risk RHD, it is not an appropriate alternative for prevention of pregnancy. Combined oral contraceptives are prone to drug- drug interactions and carry a pro-thrombotic risk and hence may not be a good alternative among most in this patient population especially those on warfarin, left atrial enlargement and a previous history of thromboembolism. This is another area of action where by clinicians should counsel patients on the pros and cons of the different methods but in the context of their heart disease and pertinent issues like drug interactions and efficacy of a particular method.

The most common reason for choice of a particular contraception method was safety (58.8%) followed by ease of use and reversibility. These are important findings, as they will help in ensuring adherence to contraception advice. The issue of reversibility is particularly important in the African context because studies have shown that despite their heart disease, these women are still wishing to conceive(47). In addition to that, reproductive decisions in our setting are still highly dependent on the male spouse and hence these factors should be taken into consideration when counselling for contraception among high risk reproductive age women with RHD.

# CHAPTER FIVE

## 5.1 STRENGTH OF THE STUDY

This was the first ever study locally to look into the clinical characteristics and echocardiographic findings among reproductive age women with RHD. To the best of the author's knowledge, it is the first study regionally that has attempted to categorize reproductive age women with RHD on the basis of their pregnancy risk in order to counsel them objectively on contraception. The results from this study have served as a a wake- up call for clinicians to provide more holistic care to RHD reproductive age women.

## 5.2 STUDY LIMITATIONS AND MITIGATIONS

This study was conducted at a tertiary level health facility which is the only center in the country that offers surgical and minimally invasive procedures for valvular abnormalities in RHD. Hence the preponderance of high risk valvular lesions like MS might represent a selected patient population awaiting intervention and hence not a true representation of the picture in the general population. However, the results are still eye- opening in the sense that high risk lesions are prevalent among reproductive age women with RHD and hence holistic care including addressing reproductive health issues should be put into consideration.

# CHAPTER SIX

## 6.1 CONCLUSION

Majority of reproductive age women with RHD are at the highest pregnancy risk based on the modified WHO classification and a very small proportion of them are on contraception. These results call for action among clinicians to offer counselling to these patients, educating them on their risk and offering appropriate contraception advice while waiting for definitive interventions.

## 6.2 RECOMMENDATIONS

Clinicians attending reproductive age women with RHD should include counselling on pregnancy risk and offer contraception advice on all encounters with these patients.

Further research should be conducted in this area especially exploring physicians and patient factors affecting counselling and contraception among reproductive age patients with RHD.

Multidisciplinary teams consisting of cardiologists and obstetricians/ reproductive health experts should be formed for holistic management of these patients.

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# APPENDICES

## ANNEX 1: INFORMED CONSENT FORM - ENGLISH VERSION

CONSENT TO PARTICIPATE IN THE STUDY ON PREGNANCY RISK AND CONTRACEPTION AMONG REPRODUCTIVE AGE WOMEN WITH RHEUMATIC HEART DISEASE ATTENDING CARE AT JKCI.

NAME_____

MRN ----------

AGE ----------

Dear Sir/Madam,

My Name is Dr. David G. Paulo a resident doctor in the department of Internal Medicine at Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a research study on **pregnancy** risk and contraception among reproductive age women with rheumatic heart disease attending care at JKCI.

I would like to conduct this study as a requirement for fulfillment of my postgraduate studies.

**Purpose of the study:**

This study aims to determine pregnancy risk and proportion of contraception among reproductive age women with rheumatic heart disease attending at the Jakaya Kikwete Cardiac Institute in order to improve patients' management.

**How to participate:**

Participants who are willing to participate in this study will have to sign a consent form.

A short interview will be done.

**Confidentiality:**

No any findings obtained will be disclosed to anybody except the attending doctors and patient herself.

**Costs:**

You will not pay any amount for your participation in this study.

**Voluntary participation and the right to withdraw from the study:**

Your participation is voluntary and you have the right to withdraw from participating in this study at any time. Whatever your decision may be, it will have no effect in any way to your rights to care and treatment.

**Risks:**

There are no risks associated

**Benefits:**

Your participation in this study will help you know about your pregnancy risk based on your diagnosis and this will help in appropriate counselling with regards to contraception.

The findings from this study will also contribute to improvement in the management of reproductive age women with rheumatic heart disease.

**INVESTIGATOR'S STATEMENT**

I the investigator have educated the research participant on the purpose and applications of this study.

Signed…… Date…….

**PARTICIPANT'S STATEMENT**

I am willingly agree to take part in this study on pregnancy risk and contraception among reproductive age women with rheumatic heart disease attending JKCI. I do this with full understanding of the purposes of the study and the procedures involved which include filling out a study questionnaire and having a physical examination done, all of which have been explained to me by Dr. David Paulo

Signature of patient----------

Signature of witness----------

Date----------

If you have questions during the course of the study, you may contact the following:

Dr. David G. Paulo
Principal Investigator
Muhimbili University of Health and Allied Sciences (MUHAS)
Department of Internal Medicine
P.O. Box 65001 Dar es Salaam.
Mobile phone:0678909948

**OR**

Dr. Reuben Mutagaywa
Supervisor for this research.
Muhimbili University of Health and Allied Sciences (MUHAS)
Department of Internal Medicine
P.O. Box 65001 Dar es Salaam.

**In case of any information about your rights as a participant in this study please contact:**

The Chairperson of Research and Publication Committee
Muhimbili University of Health and Allied Sciences (MUHAS)
P.O. Box 65001 Dar es Salaam

Tel. 022-2152489

**KIAMBATISHO II: FOMU YA OMBI LA RIDHAA**

RIDHAA YA KUSHIRIKI KATIKA UTAFITI KUHUSU HATARI INAYOAMBATANA NA UJAUZITO NA MATUMIZI YA UZAZI WA MPANGO KWA WANAWAKE WA UMRI WA UZAZI WENYE UGONJWA WA MOYO WA RUMATIKI WANAOTIBIWA KATIKA TAASISI YA MOYO YA JAKAYA KIKWETE

JINA_____

NAMBARI YA HOSPITALI_____

UMRI_____

**Kwa Bibi**

Jina langu Dr. David Paulo, mwanafunzi wa shahada ya uzamili katika chuo cha afya na sayansi shirikishi cha Muhimbili, nafanya utafiti kuangalia hatari inayoambatana na ujauzito na matumizi ya uzazi wa mpango kwa wanawake wa umri wa uzazi wenye ugonjwa wa moyo wa rumatiki wanaotibiwa katika taasisi ya moyo ya Jakaya Kikwete

**Nia ya utafiti:**

Utafii huu unalenga kuangalia hatari inayoambatana na ujauzito na matumizi ya uzazi wa mpango kwa wanawake wa umri wa uzazi wenye ugonjwa wa moyo wa rumatiki wanaotibiwa katika taasisi ya moyo ya Jakaya Kikwete.

**Jinsi ya kushiriki:**

Unaweza kushiriki katika utafiti kwa kujaza kwa hiyari yako fomu ya kuridhia kushiriki. Utafiti huu utakuwa na mahojiano kwa kutumia dodoso.

**Utunzaji wa siri:**

Taarifa zote zitakazochukuliwa katika utafiti huu zitakuwa ni siri na zitatunzwa kwa usiri na zitatumika katika utafiti huu ili ziweze kusaidia katika kuboresha huduma kwa wagonjwa.

**Gharama za Ushiriki:**

Ushiriki katika utafiti huu ni bure yaani hakuna gharama yeyote kwa mshiriki

**Hiyari ya kushiriki na kujitoa katika utafiti huu**

Ushiriki katika utafiti huu ni wa hiyari na pia ni haki yako kujitoa katika utafiti huu muda wowote unapohisi kufanya hivyo. Maamuzi yako ya kuamua kutoshiriki au kujitoa katika utafiti huu hayataathiri haki yako ya kupata huduma na matibabu.

**Madhara ya Kushiriki Utafiti:**

Hakuna madhara yeyote yatakayompata mshiriki wa utafiti huu

**Manufaa ya kushiriki utafiti huu:**

Ushiriki wako katika utafiti huu utakuwa na faida kwako kwa kuweza kujua hatari inayoambatana na ujauzito kulingana na ugonjwa wako wa moyo ili upate ushauri sahihi ikiwa ni pamoja na maswala ya uzazi wa mpango.

Nitashukuru sana kama kwa hiyari yako utaamua kushiriki katika utafiti huu.

**KAULI YA MTAFITI**

Mimi mtafiti, nakiri nimemuelewesha mshiriki wa utafiti huu kuhusu huu utafiti.

Sahihi…… Tarehe…….

**KAULI YA MSHIRIKI**

Natoa idhini mwenyewe bila aina yoyote ya kushurutishwa au kulazimishwa kushiriki katika

utafiti uliotajwa kuhusu hatari inayoambatana na ujauzito na matumizi ya uzazi wa mpango kwa wanawake wa umri wa uzazi wenye ugonjwa wa moyo wa rumatiki wanaotibiwa katika taasisi ya moyo ya Jakaya Kikwete. Nafanya hivi baada ya kuelewa taarifa zote nilizoelezwa na mtafiti, Dr David Paulo, na pia amenijibu na kunielewesha zaidi maswali niliyomuuliza.

Nimeelezewa kikamilifu kuhusu madhumuni na hali yake na naelewa kuwa nitaulizwa maswali kadhaa na kupimwa.

Pia naelewa kuwa naweza kujiondoa wakati wowote iwapo nitabadilisha mawazo.

Sahihi ya Mshiriki……

Saini ya Shahidi…….

Tarehe ……..

**Mawasiliano kwa wahusika:**

**Kwa maswali au maoni kuhusiana na utafiti huu tafadhali wasiliana na wafuatao:**

Dr. David G. Paulo

Mtafiti mkuu

Chuo kikuu cha afya na sayansi shirikishi Muhimbili

Idara ya Magonjwa ya ndani

S.L.P 65001 Dar es Salaam

Nambari ya simu: 0678909948

**AU**

**Dr. Reuben Mutagaywa**

Msimamizi wa utafiti huu.

Chuo kikuu cha afya na tiba shirikishi Muhimbili

Idara ya Magonjwa ya ndani

S.L.P 65001 Dar es Salaam**.**

**Kwa mawasiliano zaidi kuhusiana na haki zako kwenye utafiti huu kama mshiriki, tafadhali wasiliana na:**

Mwenyekiti wa tume ya tafiti na uchapishaji wa tafiti.
Chuo kikuu cha afya na tiba shirikishi Muhimbili
S.L.P 65001 Dar es Salaam
Nambari ya simu: 022-2152489

## ANNEX II: CLINICAL RESEARCH FORM

## CLINICAL RESEARCH FORM ON PREGNANCY RISK AND CONTRACEPTION AMONG REPRODUCTIVE AGE WOMEN WITH RHEUMATIC HEART DISEASE ATTENDING CARE AT JKCI.

## PATIENT RECORD FORM

I. GENERAL DATA

Study number _____Hospital Number _____

Study Date _____

NAME _____

DATE OF BIRTH _____

Date Month Year

Physical address: (District / Estate / Village / Location)

_____

Telephone Number: _____

Marital Status:

1= Married; 2= Single; 3= Widowed; 4= Separated; 5=Other

Highest Educational Attainment:

1= No formal Education; 2= Primary; 3= Secondary School; 4= College / University

Occupation:

1= Employed; 2= Self- employed; 3= Unemployed

Religion:

1= Muslim; 2= Catholic; 3= Other Christian; 4= Other

Source of funding for medical services:

1=Insurance; 2=out of pocket

II. MEDICAL HISTORY.

1. Past medical and/or social history (Circle)
    a. History of hypertension 1. Yes 2. No
    b. History of diabetes mellitus 1. Yes 2. No
    c. History of stroke 1. Yes 2. No
    d. History of cigarette smoking 1. Yes 2. No
    e. History of alcohol consumption 1. Yes 2. No
    f. History of MI 1. Yes 2. No
2. Duration since diagnosis of RHD_____ (in months)
3. Do you receive monthly prophylaxis with antibiotics? 1. Yes 2. No
4. Drugs currently used:
    a. ACEI/ ARB1. Yes 2. No
    b. Warfarin 1. Yes 2. No
    c. Calcium channel blocker 1. Yes 2. No
    d. Beta blocker 1. Yes 2. No
    e. Furosemide 1. Yes 2. No
    f. Aldactone 1. Yes 2. No
    g. Others_____
5. Are you currently experiencing any of the following?
    a) Nocturnal Cough 1. Yes 2. No
    b) Shortness of breath 1. Yes 2. No
    c) Paroxysmal nocturnal dyspnea 1. Yes 2. No

6. Physical examination findings (Circle):
    a) Weight____kg
    b) Height_____meters
    c) BMI____kg/$m^2$ 1. Normal 2. Underweight 3. Overweight 4. Obese
    d) Dyspnea 1. Yes 2. No
    e) Bilateral ankle edema 1. Yes 2. No
    f) Radial pulse rate_____bpm 1. Normal 2. Tachycardia 3. Bradycardia
    g) Radial pulse rhythm 1. Regular 2. Irregular
    h) Blood pressure_____mmHg 1. Normal 2. High 3. Low
    i) Jugular venous pressure 1. Normal 2. Raised
    j) Hepatojugular reflux 1. Absent 2. Present
    k) Apex beat 1. Not displaced 2. Displaced
    l) Murmur of: 1. MS 2. MR 3. AS 4. AR 5. TS 6. TR 7. PS 8. PR
    m) Basal crackle 1. Yes 2. No
    n) Gallop rhythm 1. Yes 2. No
    o) Congested liver 1. Yes 2. No

    Heart failure (based on Framingham criteria)_____ 1. Yes 2. No
7. NYHA classification (Circle)
    a. I
    b. II
    c. III
    d. IV

III. ELECTOCARDIOGRAPHIC FINDINGS

8. Resting 12 lead ECG findings:
    a. Rate
    b. Rhythm
    c. Axis
    d. PR interval_____
    e. QRS duration_____

f. ST segment
g. T wave
h. U wave

IV. ECHOCARDIOGRAPHIC FINDINGS

9. Valvular lesions:
    a. Mitral regurgitation 1. Yes 2. No
    b. Mitral stenosis 1. Yes 2. No . If present, area_____$cm^2$
    c. Aortic regurgitation 1. Yes 2. No
    d. Aortic stenosis 1. Yes 2. No. If present, are_____$cm^2$
    e. Tricuspid regurgitation 1. Yes 2. No
    f. Tricuspid stenosis 1. Yes 2. No
    g. Pulmonary regurgitation 1. Yes 2. No
    h. Pulmonary stenosis 1. Yes 2. No
10. Heart chambers:
    a. Left ventricular hypertrophy 1. Yes 2. No
    b. Left ventricular dilatation 1. Yes 2. No
    c. Right ventricular hypertrophy 1. Yes 2. No
    d. Right ventricular dilatation 1. Yes 2. No
    e. Left atrial dilatation 1. Yes 2. No
    f. Right atrial dilatation 1. Yes 2. No
11. Pulmonary arterial pressure_____mmHg
    a. Normal
    b. Mildly elevated
    c. Moderately elevated
    d. Severly elevated
12. Left ventricular ejection fraction_____%

V. MATERNAL RISK CLASSIFICATION

13. Modified WHO pregnancy risk class:
    a. I

b. II
c. II-III
d. III
e. IV

VI. CONTRACEPTION

14. Are you currently using any form of family planning method apart from calendar method? 1. Yes 2. No (if yes go to question 15. If no go to question 16)
15. What family planning method are you using?
    a. Implant
    b. Intrauterine device
    c. Combined oral contraceptives
    d. Barrier method
    e. Injection
    f. Sterilization (tubal ligation)
    g. Other (specify)_____
16. What were the reasons for your choice of the method above:
    a. It is safe
    b. It is easy to use
    c. It is easy to reverse
    d. Other (specify)_____
17. Did a doctor tell you that your heart is not strong enough to carry a pregnancy? 1. Yes 2. No
18. Did a doctor tell you that you should use family planning methods? 1. Yes 2. No
19. What are your reasons for not using family planning methods?
    a. Undesirable side effects
    b. Spouse does not agree
    c. Can not access family planning methods
    d. Religious reasons
    e. Other (specify)_____

VII. KNOWLEDGE OF CONTRACEPTION

20. Have you ever heard about contraception?
    a. Yes
    b. No
21. What was the source of your knowledge on contraception?
    a. Friends/peers
    b. Family members/partner
    c. Television
    d. Radio
    e. Internet
    f. Health care workers
    g. Posters/banners
    h. Other (please specify)_____

VIII. OBSTETRIC HISTORY

22. Parity_____
23. Living children_____
24. Abortions_____
25. Age of the youngest child_____
26. Desired number of children_____
27. Place of last delivery:

a. Home
b. Health facility

**KIAMBATANISHO II: FOMU YA UTAFITI**

FOMU YA UTAFITI KUHUSU HATARI INAYOAMBATANA NA UJAUZITO NA MATUMIZI YA UZAZI WA MPANGO KWA WANAWAKE WA UMRI WA UZAZI WENYE UGONJWA WA MOYO WA RUMATIKI WANAOTIBIWA KATIKA TAASISI YA MOYO YA JAKAYA KIKWETE

I. TAARIFA ZA UJUMLA

Namba ya dodoso _____ Namba ya hospitali _____

Tarehe _____ (Siku/Mwezi/mwaka)

Jina _____

Tarehe ya Kuzaliwa _____ (Siku/Mwezi/mwaka)

Anwani ya mahali: _____ (Wilaya/Kata/ kijiji / Mtaa)

Namba ya simu: _____

Hali ya Ndoa:

1= Ndoa; 2= Hamna ndoa; 3= Mjane; 4= Wameachana; 5=Nyingine

Kiwango cha elimu:

1= Hajasoma; 2= Shule ya msingi; 3= Shule ya sekondari; 4= Chuo

Chanzo cha malipo kwa ajili ya matibabu

1= Bima; 2= kutoka mfukoni

II. HISTORIA YA KIMATIBABU.

2. Taarifa za zamani za matibabu na kijamii (Zungusha jibu sahihi)
    a. Historia ya shinikizo ya damu 1. Ndiyo 2. Hapana
    b. Historia ya Kisukari 1. Ndiyo 2. Hapana
    c. Historia ya kiharusi 1. Ndiyo 2. Hapana
    d. Historia ya kuvuta sigara 1. Ndiyo 2. Hapana
    e. Historia ya kunywa pombe 1. Ndiyo 2. Hapana
    f. Historia ya mshtuko wa moyo 1. Ndiyo 2. Hapana
3. Muda tangu ugonjwa wa valvu za moyo ulipogundulika_____ (miezi)
4. Unapokea antibiotiki kwa ajili ya kinga kila mwezi? 1. Ndiyo 2. Hapana
5. Madawa anayotumia kwa sasa :
    a. ACEI/ ARB 1. Ndiyo 2. Hapana
    b. Warfarin 1. Ndiyo 2. Hapana
    c. Calcium channel blocker 1. Ndiyo 2. Hapana
    d. Beta blocker 1. Ndiyo 2. Hapana
    e. Frusemide 1. Ndiyo 2. Hapana
    f. Aldactone 1. Ndiyo 2. Hapana
    g. Nyinginezo_____
6. Je, unijisikia lolote kati ya yafuatayo?
    a. Kukohoa wakati wa usiku 1. Ndiyo 2. Hapana
    b. Kuishiwa pumzi 1. Ndiyo 2. Hapana
    c. Kuamka usiku baada ya kukosa hewa 1. Ndiyo 2. Hapana
7. Dalili baada ya chunguzi (Zungushia jibu sahihi):

a. Uzito____kg
b. Urefu_____mita
c. BMI____kg/$m^2$ 1. Kawaida 2. Uzito mdogo 3. Uzito mkubwa 4. Uzito mkubwa sana
d. Kupumua kwa shida 1. Ndiyo 2. Hapana
e. Kuvimba miguu yote miwili 1. Ndiyo 2. Hapana

f. Kasi ya mapigo katika ateri _____bpm 1. Kawaida 2. Ya juu 3. Ya chini
g. Mdundo wa mapigo 1. Kawaida 2. Isio kawaida
h. Shinikizo la damu_____mmHg 1. Kawaida 2. Juu 3. Chini
i. Shinikizo katika vena ya Jugula 1. Kawaida 2. Ya juu
j. Hepatojugular reflux 1. Ipo 2. Haipo
k. Apex beat 1. Haijasogea 2. Imesogea
l. Murmur of: 1. MS 2. MR 3. AS 4. AR 5. TS 6. TR 7. PS 8. PR
m. Basal crackle 1. Yes 2. No
n. Mapigo mwendo wa farasi 1. Ndiyo 2. Hapana
o. Ini kujaa 1. Ndiyo 2. Hapana

Kushindwa kufanya kazi kwa moyo (kwa kutumia vigezo vya Framingham) 1. Ndiyo 2. Hapana

8. Hatua iliyoainishwa ya moyo kutofanya kazi kadri ya NYHA (zungushia)

a. I
b. II
c. III
d. IV

III. MATOKEO YA ECG

9. Resting 12 lead ECG findings:

i. Mapigo ya moyo kwa dakika_____ kwa dakika
j. Mdundo 1. Kawaida 2. Isiyo ya kawaida
k. Mhimili 1. Kawaida 2. Kushoto 3. Kulia 4. Imezidi sana
l. Muda wa PR_____
m. Muda wa QRS_____
n. Kisehemu cha ST 1. Kawaida 2. Urefu wima 3. Imeshuka
o. Wimbi la T 1. Kawaida 2. Urefu wima 3. Imegeuka
p. Wimbi la U 1. Lipo 2. Halipo

IV. MATOKEO YA ECHO

10. Matatizo ya valve:

i. Mitral regurgitation 1. Ipo 2. Haipo

j. Mitral stenosis 1. Ipo 2. Haipo. Kama ipo, eneo_____$cm^2$

k. Aortic regurgitation 1. Ipo 2. Haipo

l. Aortic stenosis 1. Ipo 2. Haipo. Kama ipo, eneo_____$cm^2$

m. Tricuspid regurgitation 1. Ipo 2. Haipo

n. Tricuspid stenosis 1. Ipo 2. Haipo

o. Pulmonary regurgitation 1. Ipo 2. Haipo

p. Pulmonary stenosis 1. Ipo 2. Haipo

11. Vyumba vya moyo:

g. Left ventricular hypertrophy 1. Ipo 2. Haipo

h. Left ventricular dilatation 1. Ipo 2. Haipo

i. Right ventricular hypertrophy 1. Ipo 2. Haipo

j. Right ventricular dilatation 1. Ipo 2. Haipo

k. Left atrial dilatation 1. Ipo 2. Haipo

l. Right atrial dilatation 1. Ipo 2. Haipo

12. Pulmonary arterial pressure_____mmHg

e. Kawaida

f. Iko juu kidogo

g. Iko juu sana

h. Iko juu kupita kiasi

13. Left ventricular ejection fraction_____%

V. MGAWANYO WA HATARI INAYOAMBATANA NA UJAUZITO

14. Modified WHO pregnancy risk class:

f. I

g. II

h. II-III

i. III

j. IV

VI. MATUMIZI YA NJIA ZA UZAZI WA MPANGO

15. Kwa sasa unatumia njia yoyote ya uzazi wa mpango tofauti na kuhesabu siku? 1. Ndiyo 2. Hapana (kama ndiyo, nenda swali namba 15. Kama hapana, nenda swali namba 16)

16. Njia gani ya uzazi wa mpango unayotumia?

h. Kipandikizi
i. Kijiti
j. Vidonge vya majira
k. Kinga ya kondomu
l. Sindano
m. Kufunga uzazi (upasuaji mdogo wa mirija)
n. Nyingine (ainisha)_____

17. Sababu za chagua lako hapo juu ni zipi?

a. Ni salama
b. Ni rahisi kutumia
c. Ni rahisi kurudi kwenye uzazi
d. Nyingine (ainisha)_____

18. Umewahi kuambiwa na daktari kuwa moyo wako hauko imara kubeba ujauzito? 1. Ndiyo 2. Hapana

19. Daktari alikuambia utumie njia za uzazi wa mpango? 1. Ndiyo 2. Hapana

20. Sababu zako za kutokutumia njia za uzazi wa mpango ni zipi?

f. Madhara ya njia za uzazi wa mpango
g. Mwenzi hakubaliani na matumizi ya uzazi wa mpango
h. Siwezi kuzipata njia hizi
i. Nyinginezo(ainisha)_____

**ANNEX III: INFORMED ASSENT FORM - ENGLISH VERSION**

This informed assent form is for females aged 15-17 years old with Rheumatic heart disease attending clinic at the Jakaya Kikwete Cardiac Institute.

Dear Madam,

My Name is Dr. David G. Paulo a resident doctor in the department of Internal Medicine at Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a research study on pregnancy risk and contraception among reproductive age women with rheumatic heart disease attending care at JKCI.
I would like to conduct this study as a requirement for fulfillment of my postgraduate studies.

**Purpose of the study:**

This study aims to determine pregnancy risk and proportion of contraception among reproductive age women with rheumatic heart disease attending at the Jakaya Kikwete Cardiac Institute in order to improve patients' management.

**How to participate:**

Participants who are willing to participate in this study will have to sign a consent form.

A short interview will be done.

**Confidentiality:**

No any findings obtained will be disclosed to anybody except the attending doctors and patient herself.

**Costs:**

You will not pay any amount for your participation in this study.
Voluntary participation and the right to withdraw from the study:
Your participation is voluntary and you have the right to withdraw from participating in this study at any time. Whatever your decision may be, it will have no effect in any way to your rights to care and treatment.

**Risks:**

There are no risks associated

**Benefits:**

Your participation in this study will help you know about your pregnancy risk based on your diagnosis and this will help in appropriate counselling with regards to contraception.

The findings from this study will also contribute to improvement in the management of reproductive age women with rheumatic heart disease.

**INVESTIGATOR'S STATEMENT**

I the investigator have educated the research participant on the purpose and applications of this study.

Signed…… Date…….

**PARTICIPANT'S STATEMENT**

I am willingly agree to take part in this study on pregnancy risk and contraception among reproductive age women with rheumatic heart disease attending JKCI. I do this with full understanding of the purposes of the study and the procedures involved which include filling out a study questionnaire and having a physical examination done, all of which have been explained to me by Dr. David Paulo

Signature of patient----------

Signature of witness----------

Date----------

**KIAMBATANISHO III: FOMU YA OMBI LA RIDHAA KWA WENYE UMRI CHINI YA MIAKA 18.**

**Kwa Bibi,**

Jina langu Dr. David Paulo, mwanafunzi wa shahada ya uzamili katika chuo cha afya na sayansi shirikishi cha Muhimbili, nafanya utafiti kuangalia hatari inayoambatana na ujauzito na matumizi ya uzazi wa mpango kwa wanawake wa umri wa uzazi wenye ugonjwa wa moyo wa rumatiki wanaotibiwa katika taasisi ya moyo ya Jakaya Kikwete

**Nia ya utafiti:**

Utafii huu unalenga kuangalia hatari inayoambatana na ujauzito na matumizi ya uzazi wa mpango kwa wanawake wa umri wa uzazi wenye ugonjwa wa moyo wa rumatiki wanaotibiwa katika taasisi ya moyo ya Jakaya Kikwete.

**Jinsi ya kushiriki:**

Unaweza kushiriki katika utafiti kwa kujaza kwa hiyari yako fomu ya kuridhia kushiriki. Utafiti huu utakuwa na mahojiano kwa kutumia dodoso.

**Utunzaji wa siri:**

Taarifa zote zitakazochukuliwa katika utafiti huu zitakuwa ni siri na zitatunzwa kwa usiri na zitatumika katika utafiti huu ili ziweze kusaidia katika kuboresha huduma kwa wagonjwa.

**Gharama za Ushiriki:**

Ushiriki katika utafiti huu ni bure yaani hakuna gharama yeyote kwa mshiriki

Hiyari ya kushiriki na kujitoa katika utafiti huu

Ushiriki katika utafiti huu ni wa hiyari na pia ni haki yako kujitoa katika utafiti huu muda wowote unapohisi kufanya hivyo. Maamuzi yako ya kuamua kutoshiriki au kujitoa katika utafiti huu hayataathiri haki yako ya kupata huduma na matibabu.

**Madhara ya Kushiriki Utafiti:**

Hakuna madhara yeyote yatakayompata mshiriki wa utafiti huu

**Manufaa ya kushiriki utafiti huu:**

Ushiriki wako katika utafiti huu utakuwa na faida kwako kwa kuweza kujua hatari inayoambatana na ujauzito kulingana na ugonjwa wako wa moyo ili upate ushauri sahihi ikiwa ni pamoja na maswala ya uzazi wa mpango.

Nitashukuru sana kama kwa hiyari yako utaamua kushiriki katika utafiti huu.

**KAULI YA MTAFITI**

Mimi mtafiti, nakiri nimemuelewesha mshiriki wa utafiti huu kuhusu huu utafiti.

Sahihi…… Tarehe…….

**KAULI YA MSHIRIKI**

Natoa idhini mwenyewe bila aina yoyote ya kushurutishwa au kulazimishwa kushiriki katika

utafiti uliotajwa kuhusu hatari inayoambatana na ujauzito na matumizi ya uzazi wa mpango kwa wanawake wa umri wa uzazi wenye ugonjwa wa moyo wa rumatiki wanaotibiwa katika taasisi ya moyo ya Jakaya Kikwete. Nafanya hivi baada ya kuelewa taarifa zote nilizoelezwa na mtafiti, Dr David Paulo, na pia amenijibu na kunielewesha zaidi maswali niliyomuuliza.

Nimeelezewa kikamilifu kuhusu madhumuni na hali yake na naelewa kuwa nitaulizwa maswali kadhaa na kupimwa.

Pia naelewa kuwa naweza kujiondoa wakati wowote iwapo nitabadilisha mawazo.

Sahihi ya Mshiriki……

Saini ya Shahidi…….

Tarehe ……..