FACTORS INFLUENCING PERFORMANCE OF SCREENING METHODS FOR URINARY SCHISTOSOMIASIS AMONG SCHOOL CHILDREN IN UWANDANI PEMBA, ZANZIBAR - TANZANIA, 2017

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By

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A Dissertation Submitted in (partial) Fulfilment of the Requirements for the Degree of Master of Science (Tropical Diseases Control) of

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CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance of a dissertation entitled: ***"Factors Influencing Performance of Screening Methods for Urinary Schistosomiasis among School Children in Uwandani Pemba, Zanzibar - Tanzania, 2017"*** in (partial) fulfillment of the requirements for the degree of Master of sciences in (Tropical Diseases Control) of the Muhimbili University of Health and Allied Sciences**.**

_____

Dr. Billy Ngassala

(Supervisor)

_____

Date

DECLARATION AND COPY RIGHT

I, **Suleiman Amani**, 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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DEDICATION

This dissertation is dedicated to my family particularly my beloved wife Ms. Saada my daughters Humayra and Ruqaiya and my son Abdulhalim.

LIST OF ABBREVIATIONS

CCA	Circulating Cathodic Antigen
CDC	Centre for Disease Control
CPS	Convenient Purposive Sampling
Egg/10ml	Eggs per 10 millilitres of blood
Epg	Eggs per gram
MDA	Mass Drug Administration
MoHSW	Ministry of Health and Social Welfare
MUHAS	Muhimbili University of Health and Allied Sciences
PZQ	Praziquantel
RDT	Rapid Diagnostic Test
SCI	Schistosomiasis Control Initiatives
WHO	World Health Organization

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ABSTRACT

Background: Correct diagnosis for urinary schistosomiasis is essential for patient management, drug efficacy evaluations, and monitoring of large-scale control programs. However diagnostic performance of screening (indirect) methods varies in different endemic zones, age groups and sex especially when there is low prevalence after large scale praziquantel mass drug administration (MDA) in a school based schistosomiasis control programme.

Main Objective: To assess the factors influencing the performance of screening methods (self-reported, macro and micro haematuria and microscopy) in the diagnosis of urinary schistosomiasis after wide scale up MDA with praziquantel in a school-based schistosomiasis control programme.

Materials and methods: A cross-sectional study was conducted in Uwandani Village Chakechake District from May to June, 2017. Probability sampling applied to obtain the schools and participants of the study. Uwandani School was selected and a total of 334 participants from standard I – VI were randomly selected. A structured questionnaire was used to collect information on demographic characteristics; self reported haematuria, and status of praziquantel administration. Each participant was provided with 50mls clean, dry wide mouthed and well caped labeled plastic containers for collecting about 20ml of clean-catch, midstream urine sample between 10:00hrs and 14:00hr.

The SPSS software version 16.0 was used to make data analysis.

The diagnostic performance of dipstick screening test was compared with microscopic examination of urine for S. haematobium egg (filtration method, as the gold standard).

Results:

The prevalence of urinary schistosomiasis increased and decreased with age. The highest prevalence occur among students aged between 13 – 15 years (4.66%) and 6 – 9 years (4.33%) but lower in age between 10 – 12 years (2.0%) for both sexes, but the difference was not significant ($P > 0.05$).

The prevalence by reported haematuria was 19.3% of which the prevalence was 15% males and 4.33% females. The prevalence by reported haematuria with age group was (6%) at the age of 13-15 years and 10-12 years (5.66%) for males while the prevalence was 0% among

students aged 13-15 years and 2.0% in the age of 10-12 years in females. For pupils aged at 6-9 the prevalence was 3.33% in males and 2.33% in females.

The overall prevalence by visual haematuria was 3.7% in which (1.33%) students were males and (0.33%) were females aged 13-15 years while the prevalence in students aged 6-9 years was 0.33% in males and 1.6% in females. Those students aged at 10-12 years had 0% prevalence.

Urine dipstick results revealed that 70 participants had haematuria of which 38 were girls (24.2%) and 32 were boys (22.4%).

The overall intensity of infection was 33 (11%) participants were confirmed to have urinary Schistosomiasis, in which 17 had light infection (5.67%), where males were 9 (3%) and 8 females (2.67%). Additionally, 5 participants (1.66%) had mild infection in which males were 2 (0.67%) and 3 females (1%) and finally 11 (3.67%) had heavy infection where 5 of them were males (1.67%) and 6 female (2%).

The sensitivity and specificity of self reported haematuria was 21.2% and 81% respectively. The negative predictive value (NPV) was 89.3% while positive predictive (PPV) value was 12.1%. The sensitivity and specificity of visual examination was 33.3% and 100% respectively. The negative predictive value (NPV) was 92.4% while positive predictive (PPV) value was 100%. The sensitivity and specificity of chemical reagent strips for haematuria was 39.4%and 75.3% respectively. The negative predictive value (NPV) was 91% while positive predictive (PPV) value was 16.5%.

The logistic regression analysis showed that, sex and intensity had significant correlation with false positive results and influence the performance of self reported haematuria ($p < 0.05$ and $p < 0.001$) respectively. The intensity of infection also influenced the performance of visual haematuria and microhaematuria as ($p < 0.001$) and associated with false positive results.

Conclusion:

Among the three diagnostic tests used in this study the urine dipstick for microhaematuria has been shown to be highly performing test for rapid screening of urinary schistosomiasis influenced by the intensity of infection. The visual haematuria still remain as useful test for rapid screening of urinary schistosomiasis but the test should be confirmed by microscopy (filtration method).

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Urinary schistosomiasis is a parasitic infection caused by *Schistosoma haematobium* found in fresh water. Fresh water snails are also infected by these parasites during its life cycle, and humans when come into contact with fresh water that contains infected snails during agricultural, domestic and recreational activities are at risk of acquiring urinary schistosomiasis infection (Kabululu 2013).

Schistosoma haematobium is endemic all over the African continent as well as parts of Western Asia. It is a blood-borne trematode parasite which in the adult form dwell in the capillary plexus draining the bladder and other parts of the uro-genital system. Additionally, this parasite is dioecious, long lived and reproduces by depositing eggs in the capillary plexuses of the bladder epithelium. The eggs are hard shelled with a terminal spine. Eggs are responsible for clinical manifestation of macrohaematuria (Ibironke *et al*. 2012).

In Tanzania, urinary schistosomiasis is endemic in several areas and poses serious public health problem. According to MoHSW the prevalence of schistosomiasis in Tanzania varies from 13% to 88%, reaching 100% in some settings and the prevalence of urinary schistosomiasis was 25% in Mbeya region and 36% in Mbozi district (Kabululu 2013).

Urinary schistosomiasis is a major health problem on the islands of Zanzibar (Unguja and Pemba) located adjacent to the mainland coast of East Africa. Typically, schistosomiasis is a chronic infection causing significant morbidity (Guidi *et al*. 2010).

The prevalence of urinary schistosomiasis in Unguja Island shows significant decrease below 10% compared with Pemba Island where the prevalence is about 37.7% at Uwandani village in Chakechake district (H. Khamis. 2016 unpublished data).

Life cycle

The life cycles of *S. haematobium* involve a snail intermediate host and human as definitive host. Eggs eliminated with urine-under optimal conditions, hatch to release miracidia which swim and penetrate *Bulinus* snail (intermediate hosts). Within the snail developed into sporocysts then infective cercariae which released from the snail, swim and penetrate the skin of the definitive host (Olveda *et al*. 2013).

In human, cercariae shed their forked tail and become schistosomule which migrate through several tissues. Adult worms exist in the mesenteric venules in various locations, e.g. in the venous plexus of the bladder, also can be found in the rectal venules. Females deposit eggs in the small venules of the portal and perivesical systems. Eggs moved progressively toward the bladder and ureters, and eliminated with urine. The egg is a diagnostic stage for schistosoma parasites including *Schistosoma haematobium* (Olveda *et al*. 2013).

Accurate diagnosis is essential to obtain data regarding the distribution, prevalence and infection intensity of schistosomiasis in endemic area, and diagnostic approaches should differ at different stages of schistosomiasis control to find more sensitive and specific technique with good performance in the detection of the infection (J. Xu *et al*. 2016).

The active diagnosis of *Schistosoma haematobium* infection rely on the excretion of eggs in urine by parasitological methods such as centrifugation or urine filtration techniques, which has a low cost and can be done in field studies. Direct egg finding achieves 100% specificity and high sensitivities equivalent with high parasite burden (Eleanor *et al*. 2017). However, individuals with less than 100 eggs per gram (epg), are usually under diagnosed by parasitological method due to the loss in sensitivity post Praziquantel MDA.

Additionally, the assessment of the effectiveness of control or eradication programs after MDA is distorted. Other diagnostic methods such as dipstick, questionnaire and self reported haematuria have been proposed as complementary or in substitution and useful for mass screening in endemic areas (Elmorshedy 2015).

Nowadays, screening for urinary schistosomiasis is being conducted using various indirect diagnostic tests such as interview technique for unqualified haematuria, terminal haematuria and dysuria, visual examination of urine specimen for macrohaematuria, chemical reagent strip technique for microhaematuria and proteinuria, and immunological

method using monoclonal antibody based (mab) dipstick assay. These methods found to be simple and reliable with their productivity serving as valuable indicators of schistosomal infection among children in endemic areas (Ayele *et al*. 2008). The urinary dipstick for recognition of hematuria has long been suggested as a relatively inexpensive and potentially precise technique for detection of *S. haematobium* infection, but as similar as any diagnostic test, performance characteristics can vary with the prevalence of the targeted disease due to mass praziquantel administration (King & Bertsch 2013).

However the diagnostic performance of self reported haematuria dipstick and macrohaematuria is affected by age, sex and status of praziquantel mass drug administration. The females in menses and the urogenital tract infection are considered as confounding factors that reduces the sensitivity and specificity of the tests (Ayele *et al*. 2008).

Prevalence and intensity of schistosomiasis is often higher among children of 9 to 11 years and higher in children of 12 to 15 years (J. Aagaard-Hansen 2009).

There are several challenges (factors) that render the performance of different diagnostic tests for urinary schistosomiasis as mentioned earlier. This study will verify that, which of the above mentioned screening tests are suitable in monitoring the morbidity control programmes and in diagnosing the disease in areas with low prevalence.

1.2 Problem Statement

Indirect diagnostic methods in urinary schistosomiasis are widely used for screening high-risk populations in endemic areas. However, their sensitivity and specificity may vary in different endemic zones, age groups sex and status of praziquantel administration**.**

Sensitivity and specificity measures the intrinsic validity of a diagnostic test compared to the gold standard (microscopy). A valid test would correctly detect the presence of disease also accurately detect the absence of the disease in infected and non-infected individuals respectively. Accurate diagnosis for schistosomiasis is essential for patient management, drug efficacy evaluations, and monitoring large-scale control programs. Indirect diagnostic methods in urinary schistosomiasis are commonly used for screening high-risk populations in endemic areas.

For instance, the discrepancy in age and sex has significant implications for the use of questionnaires and urine dipstick for the selection of schools and children for treatment. Likewise, day by day variation in egg excretion and the passage of few eggs in chronically infected individual decrease the sensitivity of diagnostic measures which might lead to underestimation of the prevalence. As a result it is difficult to control the disease due to the presence of false positive and false negative results.

Different indirect methods (self reported haematuria, questionnaire and dipstick) have been compared with microscopy (filtration method) as gold standard to determine the sensitivity, specificity of the diagnostic tests. However few studies have assessed factors influencing performance of indirect tests after wide scale use of praziquantel MDA in school programmes.

This study has explored factors which influenced the performance of screening method after large scale use of praziquantel in ongoing control programs in Pemba/Uwandani.

1.3 Conceptual Frame Work

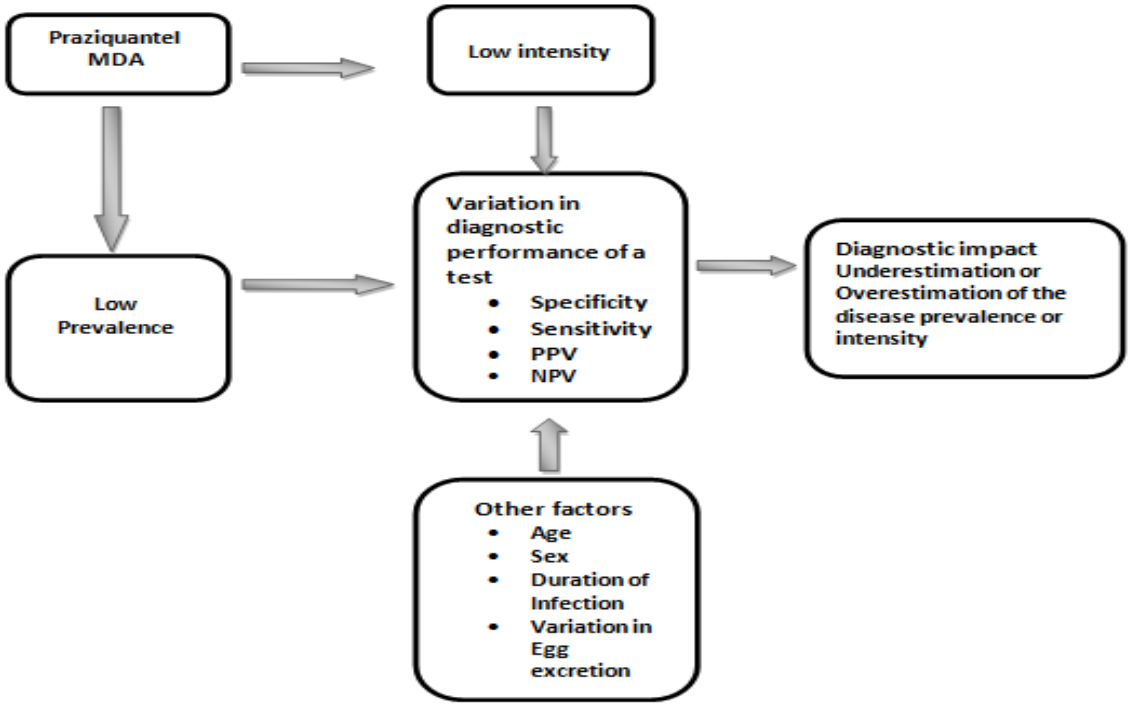

Fig 1: Conceptual frame work on factors affecting the diagnostic performance of diagnostic methods for urinary schistosomiasis.

1.4 Rationale

To detect *Schistosoma* infection in low prevalence areas is still a challenge, thus, results from this study provided the proof of which among the mentioned diagnostic techniques is sensitive, field applicable, and consistent with regular schistosomiasis screening in endemic communities where mass treatment interventions have been undertaken.

Further this study helps to show the current prevalence of urinary schistosomiasis in Uwandani Chakechake district post Praziquantel MDA and factors influenced the performance of indirect diagnostic methods.

1.5 Research Questions & Objectives

1.5.1 Questions

What is the influence of age, sex and status of praziquantel administration in the performance of screening methods (self-reported, macro and micro haematuria) in the diagnosis of urinary schistosomiasis among primary school children in Uwandani?

1.6 Objectives

1.6.1 General Objective

To assess the factors influencing the performance of screening methods (self-reported, macro and micro haematuria and microscopy) in the diagnosis of urinary schistosomiasis after wide scale up MDA with praziquantel in a school based schistosomiasis control programme.

1.6.2 Specific Objectives

1. To determine the prevalence and intensity of urinary schistosomiasis among primary school children in Uwandani shehia.

2. To determine the performance of screening methods (self reported hematuria, macro and dipstick) compared to microscopy for the diagnosis of urinary schistosomiasis among primary school children in Uwandani shehia.

3. To determine the influence of age and sex and status of PZQ administration, in the diagnostic performance of screening methods in the diagnosis of urinary schistosomiasis among primary school children in Uwandani shehia.

1.7 Literature Review

Schistosoma haematobium colonizes the venous blood vessels in the pelvis and around the urogenital tract, and causes tenderness that leads to ulceration and bleeding into the urine due to spiny eggs produced. The eggs are responsible for manifestation of macrohaematuria as one of the diagnostic method used for screening in endemic areas (King & Bertsch 2013).

Performance of Self reported and visual haematuria by age, sex, intensity and status of praziquantel MDA

The detection of haematuria by using questionnaires can be performed by taking a history of bloody urine from the participant, visual examination of bloody urine can be done by using naked eyes and dipsticks are useful for microhaematuria in mass screening but sex can affect the performance of these diagnostic methods.

Macrohaematuria is detected by direct observation of the urine specimen, which becomes visible reddish in colour. This is an important sign of heavy infection with *S. haematobium* (WHO 2011).

Visual haematuria is a different method for diagnosing urinary schistosomiasis, whereby blood in urine is visualized simply by eyes and assigned a number. The urine colour chart ranges from 1 to 4 with 1 indicating urine free of any trace of microhaematuria or proteinuria (light - yellow) and 4 correspond to dark red urine (bloody urine). Whereas number 2 and 3 grouped as brown colour correspond to visually discernable microhaematuria and proteinuria present in the urine (Ugbomoiko *et al*. 2009).

Some articles validated visual haematuria as it shown to correlate with infection intensity as measured by egg counts and can predict the prevalence of infection. This was found in a study conducted in Benue state Nigeria where filtration technique is regarded as the gold standard test. It was suggested that urine colour inspection, if used as rapid screening tool in an endemic area and it is applicable for assessing the prevalence of urinary schistosomiasis in the community. In addition to being a useful rapid field diagnostic for *Schistosoma haematobium* infection, urine colour as assessed by observation may also prove to be a marker of morbidity through proteinuria and micro haematuria (J. Xu *et al*. 2016)**.**

Another study done in Pemba Island to estimate the validity and efficiency of indirect screening methods for detecting *S. haematobium* morbidity in children aged 5-19 years revealed that, visual haematuria had the maximum specificity, uppermost overall diagnostic performance and highest positive predictive value compared to others. However its sensitivity declined notably between the evaluations, reflecting the slowing down of the prevalence of heavy infection caused by repeated treatment of all infected subjects. The specificity and efficiency of this screening method increased significantly.

The positive predictive value declined with decreasing prevalence of heavy infection (Clements *et al*. 2008).

In the 2010 study on praziquantel efficacy and prevalence of urinary schistosomiasis in Pemba using different diagnostic methods, revealed the that, overall sensitivity of visual haematuria was 52.2%, comparable to the 42.4% previously reported on Pemba Island but lower than the recently reported values of about 75% on the nearby island of Zanzibar (Guidi *et al*. 2010). As expected, sensitivity was higher in heavy infections (67.3%) than in children with light infections (47.4%). This confirms visual haematuria as an interesting indicator of heavy *S. haematobium* infections. The diagnostic performance of micro-haematuria was clearly higher, reaching an overall positivity in 77.2% of infections (Guidi *et al*. 2010).

Haematuria represents a fine predictor of *S. haematobium* infection as it correlates with serious infection levels. However, blood in urine is a nonspecific indication of schistosomiasis in areas with low endemicity and can be over- or underestimated depending on the infection prevalence in an area. Hence, haematuria cannot be used as direct pointer of infection, but only as screening method for *S. haematobium* morbidity at the individual level (Vinkeles Melchers *et al*. 2014).

Performance of Dipstick by age, sex, intensity and status of praziquantel MDA

Detection of microhaematuria requires the use of a reagent strip that is dipped into the urine specimen for about 1 minute and then compared with a colour scale supplied with the strips. Intensity of infection can be approximated according to the amount of blood detected by the strip. Because haematuria tends to be more reliable than excretion of eggs, the strips can be used at any time of the day. The method is fast, easy to perform and

highly sensitive and specific but influenced by age, sex and status of praziquantel medication (WHO 2011).

In some studies, the dipstick assay enable identification of *S.haematobium* as long as the DNA of the organisms remain intact in the sample to be tested (Adenowo *et al.* 2015)**.**

There is another study done in Ibadan district (Nigeria) on diagnostic performances of the screening methods in terms of their sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy in relation to the microscopic examination of urine sediments (Fatiregun *et al.* 2005).

The dipstick performed relatively better compared to other methods, having the highest sensitivity of 68.3% and negative predictive value of 95.6%. The specificity was 90.1% while the positive predictive value and the diagnostic accuracy were 47.3% and 87.6% respectively. These findings are within the sensitivity range of 67 to 86.3% and close to specificity range of 92.6 to 97% as well as diagnostic accuracy 90% described in previous studies in Zambia, Zimbabwe and Tanzania. However the there were variation in sensitivity by age and sex (Fatiregun *et al*. 2005).

A similar study conducted in Central Angola depicted that, urine dipstick provided sensitivity of 96% and specificity of 61.3%, with a positive predictive value; colorimetric test showed sensitivity of 52.5%, specificity of 74.6% and a positive predictive value of 77%. Proteinuria was present in 653 (51.1%) children, being more frequent in children with *S. haematobium* in urine (Cristina Bocanegra *et al*. 2015).

The use of chemical reagent strips (dipstick) has been verified as highly sensitive and specific in various endemic areas of the world (Morenikeji *et al*. 2014). In addition, the same study done in Ghana revealed that, the presence of blood on a urine reagent strip (dipstick) was 100% sensitive and 93% specific for *S. haematobium* diagnosis (Kabululu. 2013).

In a study done in Zanzibar the self reported haematuria and dipstick tests have moderate sensitivity of 70% and specificity of 92% respectively (Lyons *et al*. 2009).

The restriction of dipstick is that, it can be affected by factors such as menstruation and genitourinary tract infections (Vinkeles Melchers *et al*. 2014). A further limitation is that they are semi-quantitative and have a narrow concentration detection range. Overall, it is advised that, the history of haematuria and visual haematuria are suitable methods for preliminary screening of communities to recognize those at risk of morbidity.

Subsequently, microhaematuria (1 + positivity limit) may be the more correct method for targeting intervention at the individual level (Kabululu. 2013).

In assessing the diagnostic performance of chemical reagent strips (urine dipsticks) for the detection of hematuria as a proxy diagnosis for *S. haematobium* infection, any available published or unpublished school-age or community based population surveys should be included, irrespective of date, location, or language of report. Studies had to include paired data for comparison of both dipstick hematuria and egg output, at the per subject level, in order to provide study-specific estimates for true positive/true negative/false positive/false negative categories (Morenikeji *et al*. 2014).

S. haematobium infections are associated with haematuria on dipstick testing.

The normal coloured urine must be assessed using dipstick technique. The technique indicates whether microscopic traces of blood that are unseen by naked eye are present in a urine sample. The sensitivity of the dipstick technique is comparable to that of the urine filtration kit. And it is simple means of microhaematuria diagnosis such that someone with minimum training can use it compared to the filtration kit which requires qualified laboratory technicians with capability in using microscopes (WHO 2008).

Urine dipsticks for detection of micro haematuria in urogenital schistosomiasis are considered a rapid and inexpensive means for estimating infection prevalence.

Identification of blood in the urine micro or macrohaematuria has been successfully used as a good indicator of *S. haematobium* infection, in high prevalence communities (Elmorshedy 2015)**.**

The performance of questionnaire by age, sex, intensity and status of praziquantel MDA

The use of questionnaire in the evaluation of self reported haematuria shows considerable correlation with urine dipstick test. When results compared between sexes both questionnaires and urine dipsticks had insignificant difference between males and females as p value was > 0.05. This was shown in a study done in Mbozi district where it was depicted that; self-reported haematuria had a sensitivity of 51.5% and a specificity of 91.7% when compared with filtration method as gold standard (Kabululu. 2013).

The questionnaire technique is economically affordable, simple and easiest to use for the diagnosis of *S. haematobium* infection. It asks children if they have seen blood in their

urine over the preceded month. The answer will be '**yes**' or '**no**' of which will indicate whether the community is affected or not, but it do not tell the intensity of infection and also it is less sensitive for girls than for boys. If 30% of children are found to be positive using the questionnaire technique, approximately 50% of the community are infected (WHO 2008). In one study done in Kilombero, Tanzania, assessment of questionnaires and the parasitological results was made, data revealed strong correlation between the two diagnostic tests. The questionnaire showed a good diagnostic performance, with a moderate positive and a high negative predictive value. The questionnaire approach was rapid and cost affordable compared to the standard parasitological examinations (Kabululu 2013)

The questionnaire method is cheap to use and simple to administer. The response will tell whether urinary schistosomiasis is present in the area, but it will not tell how many eggs are present. It is also less sensitive for girls than for boys, who are more likely to self-report bloody urine. However, by definition, a child with bloody urine is already heavily infected. Using the questionnaire method, schools can be ranked from "worst affected" to "least affected" and the areas where treatment is needed most urgently can be prioritized. Due to the lack of sensitivity, the questionnaire technique should only be used to make a community wide decision, not an individual diagnosis. WHO estimates that if 30% of children are found to be positive using the questionnaire technique, approximately 50% of the community are infected (WHO 2008) . However questionnaires separately, can miss a important proportion of infected children, especially those with light infections, consequently causing difficulty towards morbidity control programmes (WHO 2011).

Another study revealed that the questionnaires alone miss a significant proportion of infected children with light infections, suggesting that *S. haematobium* blood-in-urine questionnaire is useful as indicator of severe morbidity (Webster *et al*. 2009).

Performance of microscopy on the intensity of infection by age, sex, intensity and status of praziquantel MDA

In the filtration method (microscopy) blunt-ended forceps are utilized to place a polycarbonate filter paper on a filter-holder. The filter holder are placed on and attached to the end of a 10ml syringe, from which the plunger will be removed. The syringe is filled to the 10ml mark with a well-mixed urine sample and the plunger replaced. By holding the

syringe over a beaker, the urine will slowly pass through the filter. Then, the filter holder removed and by using blunt-ended forceps, the filter is removed and placed upwards to a clean glass-slide. A one drop of normal saline is used and the mixture covered with a cover-slip. Three slides from each urine sample should be prepared by repeating the same procedure. Using a microscope, the entire filter is examined for the presence of *S. haematobium* eggs. The number of the eggs counted per 10ml of urine was recorded and the average of the three slides was calculated (Afifi *et al.* 2016).

Urine filtration for microscopic investigation of *S. haematobium* eggs is applied and considered as gold standard diagnostic method (WHO 2008). The advantage of the microscopy can tell about the intensity of infection through egg counts under observation of infected urine slides.

Microscopy demonstrate the parasite eggs in stool or urine considered as the gold standard test for diagnosing schistosomiasis required for species identification and determining the intensity of infection. However, the sensitivity may be low, especially with light infections, and it takes approximately six weeks for eggs to be detected after the initial infection.

S. haematobium eggs are usually found in urine, but may also be present in stool. Urine should be collected between 10:00 and 14:00 when maximal egg excretion occurs (Dr Craig Corcoran,*et.al* 2015).

The study performed in Yemen the combination of questionnaires, visual haematuria and urine dipsticks with microscopy as gold standard were used. The age and sex were used due to its influence on the performance in the diagnosis. The diagnostic performance of self reported dysuria and self-reported haematuria were compared with the microscopy had high to moderate sensitivity (78.6% and 46.0% respectively) with high specificity of 81.1% and 96.8% respectively (Bassiouny *et al*. 2014).

CHAPTER TWO

2.0 MATERIALS AND METHODS

2.1 Study Area

Zanzibar is a part of the United Republic of Tanzania and consists of the two main islands, Unguja and Pemba as well as a few much smaller islands.

Pemba consists two regions with four districts (Micheweni, Wete, Chake and Mkoani) and the district are sub-divided into smaller administrative units (i.e. shehias), and totalling 121 shehias (i.e. Chake 29, Mkoani 33, Micheweni 27 and Wete 32) with the estimated population of 406,848 (census, 2012).

The study was conducted in Uwandani, Chakechake district in Pemba island Zanzibar. Uwandani shehia is geographically located at eastern part with relatively 8km from Chake - Chake. There are two annual wet seasons: the Masika rains from the south lasting usually from March to June, and the Vuli rains from north-east occurring from October to November. The average annual temperature ranges between 23°C and 32°C. The main economic activities include seawater fishing and food crop production.

Uwandani has only one Primary School which is very close to Uwandani Secondary School. The Uwandani primary school had reported high prevalence of urinary schistosomiasis of 37.7% despite repeated rounds of the praziquantel administration (H. Khamis. 2016 unpublished data).

2.2 Study design

This cross-sectional survey was conducted from May to June, 2017. The study included random sampling technique in which 334 pupils were selected from 600 students by picking piece of paper labelled ‘‘OK’’ from the box containing labelled and unlabelled pieces of paper. Each student allowed to pick only one piece of paper and the one who picked the labelled piece was selected for the study. For pupils that were absent on the first day the sampling was repeated on the next day to get those who had not attended the school until the required sample size was obtained. Unfortunately only 300 students participated in the study due to heavy rains that caused death to one student who were returning home from the school just three days before the study.

The study sample recruited in the research by using proportional distribution to the number of students in each class.

2.3 Study Population

All students of Uwandani primary school were the study population.

Eligibility criteria

Inclusion criteria

- School attendant children standard 1–6, who agreed to participate after informed consent of parents/guardians

Exclusion criteria

- New pupils.
- Female children who were in menses

2.4 Variables

Independent variables

- Screening methods
- Administration of praziquantel
- Age
- Sex

Dependent variables

- Prevalence of infections
- Intensity of infections
- Sensitivity
- Specificity

2.5 Sample size calculation

Sample size of precision level for sensitivity and specificity was calculated by Buderer's formula (Buderer, 1996).

$$n = \frac{(Z1\text{-}\alpha/2)^2 \times S\,(1-S)}{L^2 \times Prevalence}$$

Where,

S = anticipated sensitivity or specificity

(Z1-α/2) = standard normal deviate corresponding to the specified size of the critical region (α)

L = absolute precision desired on either side (half-width of the confidence interval) of sensitivity or specificity.

Taking Uwandani prevalence = 37.7% (H. Khamis, 2016),

S= 91% as specificity of reagent strips in a study done in Kilosa, Tanzania.

L = 0.05

(Z1-α/2) = 1.96

n = 334

2.6 Data collection

2.6.1 Recruitment of research assistants

Two skilled laboratory technicians from NTD programme Chakechake with microscope experience were recruited and oriented on data collection and logistic arrangements were made. Information collected by the research assistants was validated by the principal researcher and the Manager of schistosomiasis control programme in the field by checking structured questionnaire.

2.6.2 Instruments of data collection

Questionnaires, 50 ml plastic containers and microscope and slides were used for data collection. The questionnaire aimed to find the socio demographic features in one part, then assessment of self reported haematuria, dysuria, frequency of micturition and status of Praziquantel administration on the other part. The questionnaire comprised 5 close-ended questions, developed in English and then translated into Swahili.

With the help of respective class and head teachers, recruited school children were assembled to a classroom where the interview was conducted to obtain social-demographic information which involve age and sex, and also assessment of participants history regarding currently passing blood in urine, their history of painful micturition (dysuria), their frequencies of micturition and also their status of Praziquantel administration by using interview method.

After the interview, the urine collection containers have been labeled by writing numbers corresponding to the questionnaire number by using a permanent marker pen.

Clean, dry, wide mouthed and well caped labelled 50ml plastic containers with respective identification number from the questionnaire were used to collect urine samples.

The urine dipstick dipped in a 10mls urine sample for observation of microhaematuria and slides, urine filters, syringe and filter holders were used for preparation of urine samples and by using microscopes the investigation of *S. haematobium* eggs identified from different urine samples.

2.6.3 Pretesting of research instruments

The study questionnaire has been tested to 20 primary school children from Mwembeladu primary school which is different from the study area in which the participants were randomly selected to check for the flow of words and recognisability of what questionnaire intend to ask is understood by the participants. Later the instructions for urine collection and the refined questionnaires have been used for final data collection. The questionnaire with 5 close ended questions developed in English and then translated into Swahili.

2.7 Data collection Procedure

The school visited first to explain the details and benefit of the study to the head teacher and class teachers and to seek consent. Also the consent of the students aged between 11 to 13 years asked from students themselves while those between 6 to 10 years the consent asked from their parents or guardians through conversation between principal investigator, class teachers and parents after being informed on the benefit of the study to the health of their children.

On a second visit to school, all children present interviewed individually and verbally by the researcher and the assistants using the questionnaire to collect demographic information and ask them if they have blood in urine or not by using Swahili language. The answer given by the students filled in the questionnaire by the principal investigator and the research assistants. Students after being informed on the benefit and objectives of the study those who accepted to participate given 50ml dry clean leak proof container with a wide mouth and well caped followed by demonstration on how to collect about 20ml of clean catch mid stream urine between 10:00 and 14:00.

2.7.1 Urine samples collection and processing.

After clear instruction on how to collect about 20ml of clean-catch, midstream urine samples, 50mls clean, dry wide mouthed and well caped labeled plastic containers distributed to the participants for urine sample collection between 10 00hrs and 14 00hrs the optimum time for optimum egg passage (WHO, 1993). Two milliliters of 10% formaldehyde then added to each sample to prevent bacteria growth and eggs hatching. Then this urine sample transferred to the NTD laboratory in Chakechake for microscopic investigation of *S.haematobium* eggs by filtration method.

2.7.2 Visual examination of urine

Screening of the collected urine samples has been done by me as principal researcher and research assistants on the site and urine observation by using naked eyes for macro haematuria and the results are recorded by using the colour code.

2.7.3 Examination of Urine for Microhaematuria

A chemical reagent strip (Urine 10 parameters, Anti VC interference ability, United Kingdom) dipped into the container containing urine for 5 seconds to test for occult blood. The resulting change in colour of the strip has been compared with the colour chart in a container of strips to estimate the amount of blood in the urine, and then the results recorded as negative, +, ++ or +++ as per manufacturer recommendations.

2.7.4 Examination for *Schistosoma haematobium* egg

After being screened, the collected urine samples transferred to Laboratory by me as a principal researcher and research assistants in a large container, for parasitological examination using urine filtration technique as a reference test/gold standard test for *S. haematobium* egg presence and count. The eggs excreted in urine were trapped on polycarbonate filters with a fine pore size of 8–30 μm after 10 ml of a well shaken mid-day urine sample is passed through a syringe. Eggs on the filter examined and counted under a microscope. Infection intensity is expressed as the number of eggs per 10 ml of urine with a threshold of 50 eggs distinguishing between light and heavy infection. This method is easy to perform, but it lacks sensitivity to detect very light infection intensities and is affected by day-to-day variation in egg output. Hence, multiple filtrations over consecutive days were carried out to detect light infections.

Intensity of infection was measured by counting number of eggs/ 10ml of urine. Intensity ranged from 1 to 300, with median egg count of 3 eggs. Categorizing infection intensity as; light infection 1 - 29eggs/ 10 ml urine, moderate infection 30 – 49eggs/ 10 ml urine, heavy infection 50 -300 eggs/ 10 ml urine (Guidi *et al.* 2010).

2.8 Management of Cases

All positive results of *S. haematobium* were delivered to the parents or guardians of the students and referred to the Chakechake district schistosomiasis control programme manager for management. All children with microscopically positive results were treated and the remaining pupils were given praziquantel MDA by NTD programme manager two weeks after data collection to prevent more infections.

2.9 Data Entry and Analysis

Data entry and cleaning was done by using SPSS 16.0 software. The analysis has been done using correlation coefficients to find the correlation of the questionnaire and reagent strip results with the gold standard parasitological data was done using diagnostic accuracy tests. Sensitivity, specificity, positive and negative predictive values (PPV and NPV) has been calculated.

The chi- squared test, multinomial logistic regression and bivariate correlation analysis used to compare the performance of the diagnostic tests and the factors influencing the performance of the diagnostic methods of urinary schistosomiasis in relation to the prevalence, sensitivity and intensity of infection. (95% CI, $P < 0.05$ considered as significant).

2.10 Ethical Consideration

The study protocol was approved by the Research and Publication Committee of Muhimbili University of Health and Allied Science (MUHAS). The permission to conduct the study at the study area obtained from the Zanzibar Medical Research Centre (ZAMREC), District Education Officer through District NTD programme manager Chakechake.

Through teachers, parents were informed on the benefit of the study to their children's health an informed consent obtained from school children after clear instruction on the benefit of the study to student's health prior to conducting the study**.** Also the confidentiality was assured through anonymity (i.e. no names but only code numbers was used), answers to questionnaires including results for urine specimens handled carefully and restricted to unauthorized access. Students who accepted themselves to participate after being informed on the benefit of the study to their health were included in the study.

There was close communication on laboratory results with the NTD programme manager, infected pupils and their parents or guardians through their teachers. Those who found infected (egg positive) were treated by the NTD programme manager using praziquantel accordingly.

2.11 Study Limitation

Out of 334 participants from the sample size, only 300 students participated in the study at the school on head teachers call during the school vocation programme in the end of May, while the ethical clearance provided in 5th of June this year.

The study conducted during the school emergency vocation period, this lead the researcher to follow the students in their villages to complete the sample size but it reached 300 missing the rest 34 participants.

Also heavy rain fall caused difficulties in reaching other students at their homes as the paths were flooded by ponds, as well as students were not easy to reach the school after they have been called by principal due to heavy rains that caused death to one student who was returning home from the school three days before the study.

The use of a single urine sample to examine infection status could have underestimated *S. haematobium* prevalence rate. This was because of time constraints and funds but more than one sample could be taken to verify the results.

CHAPTER THREE

3.0 RESULTS

3.1 Social Demographic Characteristics

Only 300/334 (89.8%) pupils participated in the study and ll 300 pupils submitted their urine specimens. The mean age was 10.4 (SD = 2.34) ranging between 6 to 15 years.

Six classes of the Uwandani primary school participated in data collection and most of the participants came from standard 2 and 4 (22.7% and 20.3%, while standard 1 and 3 contributed 17.3% and 18.3%, with standard 5 and 6 least participants 11.3% and 10% respectively. **(Table 1 and 2).**

Table 1: Distribution of the study participants by age and sex

Age group (Years)	**Males**		**Females**		**Total**	
	Number	**Percentage %**	**Number**	**Percentage %**	**Number**	**Percentage %**
6 - 9	53	17.7	55	18.3	108	36
10 - 12	51	17	77	25.7	128	42.7
13 - 15	39	13	25	8.3	64	21.3
TOTAL	143	47.7	157	52.3	300	100

Table 2: Distribution of study participants by number and classes

Class (STD)	**I**	**II**	**III**	**IV**	**V**	**VI**
Number of participants	52	68	55	61	34	30
Percentage %	22.7	20.3	17.3	18.3	11.3	10

3.2 Status of Praziquantel administration

Majority of pupils (287/300, %) had taken praziquantel at least once during praziquantel MDA campaign. Only 13 (4.3%) pupils had not taken praziquantel. This is because they were late registered and were absent at the time of school praziquantel MDA. **(Table 3)**.

Table 3: Praziquantel MDA administered in Uwandani Primary School

Praziquantel administration	**Number of students**	**Percentage** %
Once	33	11
Twice	119	39.67
Thrice	69	23
Fourth	52	17.33
Fifth	14	4.67
None	13	4.33
Total	**300**	**100**

3.3 Prevalence of Urinary Schistosomiasis

3.3.1 Prevalence of Urinary Schistosomiasis by self reported haematuria

The prevalence of reported haematuria was 19.3% (58/300) in which 45 pupils were males (15%) and 13 were females 4.33%. The reported haematuria by age group shows that, prevalence is high in male students within the age of 13-15 years (6%) and 10-12 years (5.66%) while the prevalence in females was 0% among students aged 13-15 years and 2.0% in the age of 10-12 years. For pupils aged at 6-9 the prevalence was 3.33% in males and 2.33% in females **(Table 4).**

Also observation shows that, males reported more cases of blood in urine than females but the difference was not statistically significant ($X^2 = 0.85$, $P > 0.05$and $df = 1$). Also, when age was considered participants aged 10 – 12 years 128 (42.66%) had more frequently reported on blood in urine than other age groups however the difference was not statistically significant ($P > 0.05$ and $df = 9$), similarly, those who had taken PZQ once (11%) and fifth (4.67%) had reported few cases of blood in urine together with those that are not taken PZQ at all (4.33%) compared to those who taken PZQ twice (39.67%), thrice (23%) and fourth (17.33%). But the difference was not statistically significant as ($X^2 = 5.38$, $df = 5$ and $P > 0.05$).

3.3.2 Prevalence of Urinary Schistosomiasis by Visible haematuria

The overall prevalence of visual haematuria was 3.6% in which 4 (1.33%) students were males and 1 (0.33%) were females aged 13-15 years while the prevalence in students aged 6-9 years was 0.33% in males and 1.6% in females **(Table 5)**. Those students aged at 10-12 years had 0% prevalence.

Those 11 students observed with bloody urine considered as positive while the remaining 289 (96.3%) students with clear yellow urine or light brown urine were considered as negative.

The chi-square analysis predicted that, age and sex had no significant relationship with visual haematuria as P value for self reported haematuria was ($P > 0.05$, $X2=17.96$, $N=300$).

3.3.3 Prevalence of Urinary Schistosomiasis by microhaematuria

Classifications were made based on the colour change in the chemical reagent strips after being dipped in the urine samples. Of 300 students 70 (23.3%) were reagent strip positive in which 54 (18%) were ‘‘+’’ haematuria, 13 (4.3%) were ‘‘++’’ and only 3 students (1%) were ‘‘+++’’. Dichotomization was done in a manner that, those pupils that are revealed either +, ++ or +++ haematuria, were considered as positive for chemical reagent strips for microhaematuria 70 (23.3%) and 230 (76.7%) were negative.

The prevalence by age indicated that a total of 70 (23.3%) children were positive for microhaematuria in which those of age between 10 – 12 years old, 32 (10.66%) had the highest prevalence of infection followed by pupils aged 6-9 years 22 (7.32%) while the least prevalence 16 (5.32%) showed by the participants aged 13-15 years. Table 6.

Nonetheless, difference between microhaematuria and age was statistically significant ($X^2 = 39.78$, $df = 27$, $P < 0.05$). When sex was considered girls 38 (12.66%) had more of microhaematuria than boys 32 (10.66%) although there was no significant difference in the occurrence of microhaematuria between the sexes ($X^2 = 3.99$, $df = 3$, $P > 0.05$).

A statistically significant association was observed when chemical reagent strip was compared with visual haematuria ($P < 0.05$, $X^2=17.96$, $N=300$).

3.3.4 Prevalence of Urinary Schistosomiasis by microscopy

All 300 urine samples were filtrated after screening for self reported haematuria, visible haematuria and microhaematuria by urine dipstick, then microscopic examination under X 40 objective lens was performed. In a total of 300 participants 33 students (11.0%) were positive for *S. haematobium* infection (**table 6**).

The prevalence of urinary schistosomiasis increased and decreased with age. The highest prevalence occur among students aged between 13 – 15 years (4.66%) and 6 – 9 years (4.33%) but lower in age between 10 – 12 years (2.0%) for both sexes, but the difference was not significant (X^2 = 37.47, df = 27, P > 0.05). The prevalence was slightly higher in females (5.67%) than in males (5.33%) but the difference was not statistically significant (X^2 = 0.34, df = 3, P > 0.05). On the other hand the prevalence vary with the praziquantel administration in which those students that had taken PZQ five times has the lowest prevalence (7.1%) compared to those who taken once (9.1%) and twice (9.2%), but this difference has no significant implication in the statistics as P value is greater than expected in 95% CI (P > 0.05).

Table 4: Prevalence of Urinary schistosomiasis

Age group	**Prevalence of reported haematuria %**		**Prevalence of Visual haematuria %**		**Prevalence of microhaematuria %**		**Prevalence of microscopy %**	
	Male	Female	Male	Female	Male	Female	Male	Female
(6-9)	3.33	2.33	0.33	1.6	2.66	4.66	2.0	2.33
(10-12)	5.66	2.0	0.0	0.0	4.33	4.33	1.0	1.0
(13-15)	6.0	0.0	1.33	0.33	3.66	1.66	2.33	2.33
Total	**14.99**	**4.33**	**1.69**	**1.93**	**10.65**	**12.65**	**5.33**	**5.67**

3.6.2 Intensity of Infection

Intensity of infection was thus characterized as no infection (0 egg/10ml of urine), light infection (1-9 egg/10ml of urine), moderate infection (10-49 eggs/10 ml of urine) and heavy infections (≥50 eggs/10 ml of urine). (Morenikeji et al. 2014)

Out of 33 (11%) participants who were confirmed to have urinary Schistosomiasis, 17 had light infection (5.67%), where males were 9 (3%) and 8 females (2.67%). Additionally, 5 participants (1.66%) had mild infection in which males were 2 (0.67%) and 3 females (1%) and finally 11 (3.67%) had heavy infection where 5 of them were males (1.67%) and 6 female (2%). **(Table 5).**

The prevalence of heavy infection was slightly higher among the females 2% than the females 1.67%.

A positive correlation observed on comparison between intensity of infection with age and sex of participants. It was shown that, the intensity of infection increase as the age of the participants increase ($r = 1$, $P > 0.05$). Prevalence of heavy infection was particularly highest in the age between 6 – 9 years followed by age of 13 – 15 and light intensity was more between age of 10-12 and 13 – 15 years simultaneously. Meanwhile the correlation analysis predicted the negative correlation when status of praziquantel administration compared with the intensity of infection ($r = -0.12$, $P > 0.05$).

Table 5: Intensity of Infection

Age group (years)	**Males Infection Intensity**				**Females Infection Intensity**			
	Light	Mild	Heavy	**Total**	Light	Mild	Heavy	**Total**
6-9	5 (83.3%)	0 (0%)	1 (16.6%)	**6**	1 (14.3%)	1 (14.3%)	5 (71.4%)	**7**
10-12	2 (66.6%)	1 (33.3%)	0 (0%)	**3**	2 (66.7%)	1 (33.3%)	0 (0%)	**3**
13-15	2 (28.6%)	1 (14.3%)	4 (57.1%)	**7**	5 (71.4%)	1 (14.3%)	1 (14.3%)	**7**
Total	**9 (52.9%)**	**2 (40%**	**5 (45.5%)**	**16**	**8 (47.1%)**	**3 (60%)**	**6 (54.5%)**	**17**

3.7 Performance of Diagnostic methods

3.7.1 Performance of self reported haematuria

Using urine microscopic examination as a gold standard, the sensitivity and specificity of self reported haematuria was 21.2% and 81% respectively. The negative predictive value

(NPV) was 89.3% while positive predictive (PPV) value was 12.1% (Table 6). The higher the negative predictive value and lower positive predictive value indicates the low prevalence in the area and it is good prediction for success of the control programme (*Krauth et al.* 2015).

3.7.2 Performance of Visual haematuria

With microscopic examination of urine regarded as a gold standard, the sensitivity and specificity of visual examination was 33.3% and 100% respectively. The negative predictive value (NPV) was 92.4% while positive predictive (PPV) value was 100% (Table 6). The higher positive predictive value and lower NPV of the visual haematuria predicts the high intensity of infection as bloody urine in *Schistosoma haematobium* infection related to large number of eggs.

3.7.3 Performance of Microhaematuria

The performance of chemical reagent strips when using urine microscopic examination as a gold standard was as follows, sensitivity and specificity of chemical reagent strips for haematuria was 39.4%and 75.3% respectively. The negative predictive value (NPV) was 91% while positive predictive (PPV) value was 16.5% (Table 6). This also indicates the low prevalence of urinary schistosomiasis in Uwandani and shows successful decreasing of the infection which is good news in the control programme (Krauth *et al.* 2015).

Table 6: Performance of Diagnostic methods compared with microscopy

Criterion assessed	Self reported haematuria	Visual haematuria	Microhaematuria
True positives	7	11	13
False positives	51	0	66
True negatives	216	267	201
False Negatives	26	22	20
Sensitivity	7/33 = 21.2%	11/33 = 33.3%	13/33 = 39.4%
Specificity	216/267 = 81 %	267/267 = 100%	201/267 = 75.3%
Positive predictive values	7/58 = 12.1%	11/11 = 100%	13/79 = 16.5%
Negative predictive values	216/242 = 89.3%	267/289 = 92.4%	201/230 = 91%

3.8. Influence of Age, Sex, intensity and Status of praziquantel MDA on Performance of self reported haematuria

Pupils aged 13-15 years self reported haematuria had higher sensitivity and positive predictive value respectively with higher specificity and negative predictive value. Compared to the students aged between 10-12 and 6-9 years. The pupils at age (6-9) had more false positive results of self reported haematuria compared to the age (10-12) and 13-15 years.

This means the participants aged between13-15 are at higher risk of schistosomiasis infection than in students aged between 6-9 and 10-12 years. However the logistic regression analysis predicted age had insignificant negative correlation in false positive results (CI 95%: $p > 0.05$, $r = -0.35$).

Male participants had higher sensitivity, positive predictive value, specificity and negative predictive value of self reported haematuria than females. The higher number of positive predictive value in males predicted that, males are at higher risk of infection compared to females. However the multinomial logistic regression and Pearson's correlation analysis predicted significant association of false positive results in males ($p < 0.001$, $r = 0.243$ and OR = 1.77) and females ($p < 0.001$, $r = 0.243$ and OR = 0.44).

The performance of self reported haematuria by intensity of infection shown that the majority of pupils were in light (17/33) and mild (5/33) infection intensity and few (11/33) were in high intensity this causes difficult to report on the presence of blood in urine since the bloody urine associated with high infection intensity in pupils with low and mild infection. The chi-square test and logistic regression analysis predicted the intensity of infections had significant association and positive correlation with false positive results of reported haematuria 95% CI: $p < 0.05$, $r = 0.14$).

The sensitivity and positive predictive value of self reported haematuria was higher among participants who taken praziquantel MDA twice compared to participants taken praziquantel three, four and five times.

Those taken praziquantel MDA four and five times the self reported haematuria had many false negatives (6/7) while pupils taken MDA twice had more true positives (3/7) and fewer false positives (4/7). This means the praziquantel MDA influence the false positive results of reported haematuria. However the chi-square test and correlation analysis predicted insignificant negative correlation between praziquantel MDA and the performance of self reported haematuria ($p > 0.05$ and $r = - 0.06$).

3.8.1 Influence of Age, Sex, intensity and Status of praziquantel MDA on Performance of Visual Haematuria

The sensitivity and positive predictive value of visual haematuria was higher among pupils aged between 6-9 years compared to other age groups. Participants aged 10-12 years associated with the highest false positive results (11/11). The multinomial logistic regression analysis predicted insignificant positive correlation of age and false positive results of visual haematuria (95% CI: $p > 0.05$, $r = 0.01$).

The sensitivity and specificity of visual haematuria among females was slightly higher compared to males. Males were associated with more false positive results than females. The bivariate correlation analysis predicted insignificant positive correlation of false positive results of visible haematuria and sex (95% CI: $p > 0.05$, $r = 0.008$).

33 participants diagnosed by microscopy only 11 pupils had highest intensity. The results of visual haematuria shown that, those diagnosed with highest intensity had bloody urine (macrohaematuria) with 100% positive predictive values and lack false positive results. The multinomial logistic regression analysis shown that, there was significant negative correlation between intensity of infection and presence of false negative results of visual haematuria (95%CI: $p < 0.001$, $r = -0.89$).

The sensitivity and specificity of visual haematuria among students who taken praziquantel only twice was higher compared to those taken MDA thrice, fourth and fifth times. Pupils taken praziquantel five times had slightly more false positive results (11/11) than those taken three (10/11) and two times (9/11) times. This means the praziquantel MDA influences the false positive results of visual haematuria when compared to microscopy as gold standard.

However the logistic regression, bivariate correlation and chi-square test analysis predicted that, there was insignificant negative correlation of praziquantel MDA and false positive results of visual haematuria ($p > 0.05$, $r = -0.035$ and $X^2 = 12.16$).

3.8.3 Influence of Age, Sex, intensity and Status of praziquantel MDA on Performance of Urine dipsticks

The sensitivity and specificity of microhaematuria was higher among pupils aged 10-12 years compared to other age groups 6-9 and 13-15. Participants aged 13-15 had more false positive results compared to 6-9 and 10-12 years. The bivariate correlation and logistic regression analysis shown that, age had insignificant positive correlation with false positive results of urine dipsticks ($p > 0.05$, $r = 0.007$).

The sensitivity and specificity of urine haemasticks was higher in males compared to females. Females associated more with false positive results of microhaematuria compared to males. However the logistic regression analysis predicted that, sex had insignificant negative association with the false positive results of microhaematuria (95% CI: $p > 0.05$, $r = -0.032$).

The chemical reagent strips was more sensitive in which pupils with low, mild and high infection intensity were detected with microhaematuria. The test gave more false positive results (66/79) and few true positives (13/79) when compared with the filtration method. This means the microhaematuria also caused by other unknown factors rather than urinary schistosomiasis. The results of multinomial logistic regression and correlation analysis predicted significant positive correlation of intensity and the performance of urine dipsticks (95% CI: $p < 0.001$, $r = 0.164$).

When status of praziquantel MDA considered sensitivity and specificity was higher among participants taken praziquantel twice compared to those taken praziquantel MDA four and five times. Pupils who taken praziquantel four and five times had more false positive results compared to those taken praziquantel once and twice. This implies that, the praziquantel MDA influenced the performance urine dipsticks.

The logistic regression and bivariate correlation analysis predicted insignificant negative correlation between praziquantel MDA and presence of false positive results in microhaematuria (95% CI: $p > 0.05$, $r = -0.054$)

CHAPTER FOUR

4.0 DISCUSSION

4.1 Introduction

For patient management of returning travellers and for different stages of a schistosomiasis control programme, suitable diagnostic tools are essential. Tools for the rapid identification of *Schistosoma haematobium* infection in high-risk communities at the beginning of a control programme like simple school-based questionnaires and for an estimation of prevalence and intensity of infection in morbidity controls situation such as microscopy are available and recommended by the World Health Organization (WHO). (Utzinger *et al.* 2015)

Therefore diagnostic tools that are highly sensitive and specific, and hence appropriate for monitoring and surveillance, post transmission control and confirmation of elimination have been suggested for wider use.

4.2 Prevalence of Urinary Schistosomiasis

In this study, the prevalence of urinary schistosomiasis observed in Uwandani Primary school was 11% which is lower when compared to 37.7% that was reported in pilot studies done by Juma H. Khamis in 2016. This may be explained by the six rounds of ongoing Praziquantel MDA programme which have been performed in Uwandani primary school Chakechake since 2012 to July, 2017. This is low prevalence according to the WHO classification where by prevalence rates below 25% are seen to be low (WHO, 2008). This means the ongoing Praziquantel MDA is effective in reducing the number of schistosomiasis infection in Uwandani.

The reduction of schistosomiasis by the use of Praziquantel MDA treatment and prevention programme has been successful in other areas in the world like Sudan (Afifi *et al.* 2016) and in Chad where the prevalence reduced to 2.2% (Krauth *et al.* 2015). Also in the study of praziquantel efficacy in the treatment of urinary schistosomiasis done in Pemba has shown that 7 weeks after initial treatment of *S. haematobium* infected children has shown a cure rate of 95% (Guidi *et al*. 2010). These follow the similar pattern to the study done in Mbozi district where the Praziquantel MDA reduced the prevalence form 36% 2010 to 7.9% 2013 (Kabululu 2013).

The prevalence of urinary schistosomiasis was slightly higher in males 11.2% than in females 10.9%. This may be contributed by the preference of water contact of males than females where swimming, fishing causes boys to contact with fresh water ponds rather than girls and acquire *S.haematobium* parasites but the difference was not significant (P > 0.05). This is similar to the study done in Mbozi where prevalence in males aged 9-12 years was high than in females (Kabululu 2013). Ibadan (Nigeria) , Accra (Ghana) and Yemen (Bassiouny *et al*. 2014) but the difference observed in statistical analysis as this study shown insignificant differences between sexes while other studies revealed the significant difference in prevalence among males and females.

4.3 Intensity of Infection

This study has shown that, the intensity of infection increase as the age of the participants increase similar to the study done in Mbozi (Kabululu 2013), Accra (Tetteh-quarcoo *et al.* 2013) and Yemen (Bassiouny *et al.* 2014). But the intensity of infection differs among males and females but the difference is not statistical significant (P > 0.05).

4.4 Diagnostic Performance of self reported haematuria

The presence of blood in urine (haematuria) has been associated with *S. haematobium* infection since ancient times, but used as an indirect indicator for this parasite because it sometimes its sensitivity is at variance with the microscope (Lengeler *et al*. 2002). If 30% of children are found to be positive using the questionnaire method, approximately 50% of the community are infected (WHO 2008).

In this study self reported haematuria had lowest sensitivity of 21%, compared to a study done in Mbozi, District 51.5 % Tanzania mainland as well as different from the study done in Ghana 53% (Kabululu 2013) and Southeastern Nigeria 29.7% (Okeke & Ubachukwu 2014). Also different from another study in Ghana 25% (Tetteh-quarcoo *et al.* 2013). Meanwhile the sensitivity in this study was higher 21.2 % compared to the study done in Unguja 15.7% (Sousa-Figueiredo *et al*. 2009). This implies that the performance of self reported haematuria is good but lower due to low prevalence of urinary schistosomiasis in Uwandani Pemba.

Specificity of self reported haematuria in this study was 80.9% lower compared to the findings from Mbozi 91.7% (Kabululu 2013), also lower when compared with a study done in Ibadan Nigeria, 96.1% (Fatiregun *et al*. 2005), Unguja 96.6% (Sousa-Figueiredo *et al*. 2009) and Southeastern Nigeria 87.9% (Okeke & Ubachukwu 2014). Further more in this study self reported haematuria has lower specificity 80.9% in comparison with the study in Yemen 96.8% (Bassiouny *et al*. 2014).

The negative predictive value was 89.3% lower compared with study done in Mbozi 95.7% also lower compared to Kilombero findings 100% but higher compared to Dar es salaam 67% (Kabululu 2013).

The findings from this study shown the lower positive predictive (PPV) value of 12.1% compared to the study done in Dar es salaam 67%, Kilosa 92% and Kilombero 31% (Kabululu 2013) , also lower compared to the study done in Southeast Nigeria 47.8% (Okeke & Ubachukwu 2014). In this case when we compare between the two predictive values, we find the Negative predictive value is higher 89.3% compared to the positive predictive value 12.1%. This implies that, the prevalence is low as the PPV value and it is proportional to the prevalence while the NPV is inversely related with the prevalence (Krauth *et al.* 2015).

This study depicted that, males reported more cases of blood in urine (31.5% prevalence) than females, prevalence was (18.3% prevalence) but the difference was not statistically significant ($P > 0.05$). A similar trend was observed in Mbozi district, Tanzania in which males reported more cases of blood in urine than females (Kabululu 2013). Also by age participants aged 13 – 15 years report blood in urine more frequently (46.2% prevalence) than other groups though the difference was not statistically significant ($P = > 0.05$). This is similar to the study done in Lusaka, Zambia where the higher prevalence observed among participants aged (13-17) for both gender (Agnew-Blais *et al*. 2009).

4.5 Diagnostic performance of Visual Haematuria.

The visual examination of urine was more sensitive 33.3% in comparison to reported haematuria. However this sensitivity is lower compared with other studies. For example in the study done in Mbozi where sensitivity was 42.4% (Kabululu 2013), and higher compared to the study done in Ibadan, Nigeria where sensitivity was 16.7% (Fatiregun *et al*. 2005).

Low sensitivity of visual haematuria might have been owing to incompetence in the collection of urine by the students, they were unsuccessful to abide on the instructions with regards to collection of terminal stream of urine which is expected to contain blood. This may not support visual method to be operationally effective among the school children, additionally it can be due to the complexity in interpreting colour of urine to determine if it contains blood or not, which to a certain extent is subjective, hence resulted to 22 participants with false negatives.

On the other side visual haematuria had highest PPV 100% and higher specificity 100% slightly comparable with the study performed in Angola where specificity was 97.5% and PPV was 97.2%. Positive correlation between visual haematuria with filtration method as gold standard was shown in this study. For this reason visual examination of urine remains as effective method for preliminary diagnosis of urinary schistosomiasis as it is simple to perform and it is less prone to recall bias compared to self reported haematuria.

4.6 Performance of Microhaematuria

This study has shown that, chemical reagent strips had the highest sensitivity 39.4% among those diagnostic methods, follow the similar pattern but lower compared to other studies done in Pemba Island 98%, Ghana 100%, Ethiopia 80%, 78.8% Mbozi Tanzania (Kabululu 2013) and Nigeria 68.3% (Fatiregun *et al*. 2005). Also the sensitivity of urine dipstick in this study was lower compared to the study done in Cubal Angola where sensitivity was 96% twelve times higher and 76% in the study done by Ochodo University of Amsterdam (Eleanor *et al*. 2017). This due to the low prevalence status in Uwandani and the effect of ongoing praziquantel MDA reduces the worm burden and egg shading in the urinary bladder. This implies that, the urine dipstick is more reliable in highly endemic areas rather than in low prevalence areas (Cristina Bocanegra *et al*. 2015).

The urine dipsticks in this study revealed the lowest specificity value of 75.3% in comparison to other diagnostic tests. Additionally in comparison with other studies the specificity of chemical reagent strips for haematuria in this study was lowest in contrast as 81.5% in north Côte d'Ivoire, Chad was 83.5 % and south Côte d'Ivoire was 92.3 % (Krauth *et al.* 2015). Also the specificity of urine dipsticks was lower compared to the study done in rural areas of Nigeria (Morenikeji *et al*. 2014) and Kenya where the specificity of urine haemasticks was 98% (Sheele *et al*. 2013).

The positive predictive (PPV) value was 16.5% higher compared to the study done in north Côte d'Ivoire7.1 %, but lower compared to the study done in south Côte d'Ivoire 97.7 % and in Lake Chad area 28.2 %. The negative predictive value (NPV) was 91% lowest compared to the study done in Yemen 94.5% (Bassiouny *et al.* 2014) and Chad 98.6% (Krauth *et al*. 2015) but higher compared to other studies 69.9% in rural areas of Nigeria, (Morenikeji et al. 2014), Nigerian school children 62% (Ugbomoiko *et al*. 2009) and 25.2% Mbozi Tanzania (Kabululu 2013).

4.7 Influence of Age, Sex, intensity and Status of praziquantel MDA on Performance of Diagnostic methods.

4.7.1 Self reported haematuria

When the age was considered in this study the self reported haematuria performed well in participants aged 13-15 where the sensitivity was higher compared to 6-9 and 10-12 years, but the age 6-9 years had more false positive results with few true positives. Pupils aged 13-15 had more true positive results compared to other age groups. Therefore the age influenced the performance of self reported haematuria because this age group has high water contact through swimming and fishing in freshwater ponds compared to other age groups (Ugbomoiko *et al*. 2009)**.** However the logistic regression analysis results shown that, age and status of praziquantel MDA was not significant in the performance of self reported haematuria and not correlate with false positive results while sex and intensity had significant correlation with the performance of reported haematuria and associated with false positive results. This follows a similar pattern as the study done in Yemen where self reported haematuria performed well in males participants than in females (Clements *et al*. 2008) and (Bassiouny *et al*. 2014).

4.7.2 Visual Haematuria

As age was considered the sensitivity was in the participants aged 6-9 and positive predictive value was higher compared to the students aged 10-12 and 13-15 years. The decrease in sensitivity of visual haematuria also explained in the study done in 2010 where the performance of visual haematuria lowered in the participants in older age 13-16 years compared to the participants aged 5-9 years (Guidi *et al*. 2010).

The performance of visual haematuria in this study the sensitivity and specificity was slightly higher in females than males. This is comparable to the study done in Nigeria where the performance of visual haematuria was higher in females compared to males and the method was highly specific as specificity was 96% (Fatiregun *et al*. 2005).

The study revealed that, the performance of visual haematuria decreased with the increase of praziquantel MDA. The sensitivity is higher to the participants who taken PZQ twice and fourth compared to those taken praziquantel five times where the visual haematuria was not sensitive 0%. This follow the same trend as reported in the study done in Mbozi where sensitivity of visual haematuria decrease as the intensity of infection lowered by praziquantel MDA (Kabululu 2013). The logistic regression shown that, factors such as age, sex and status of praziquantel MDA were not significant in the performance of visual haematuria and not correlate with the false positive results ($p > 0.05$). The intensity of infection was significantly associated with the false positive results and influenced the performance of visual haematuria ($p < 0.001$)

4.7.3 Microhaematuria

When age considered as a factor the urine dipstick was most sensitive among participants aged 13-15 compared to 10-12 and 6-9 years. However the microhaematuria was most specific among all age groups. The logistic regression and correlation analysis shown that, age had insignificant correlation on the performance of urine dipstick. The study agreed with the results from North Africa where the performance of urine dipstick was 65% independent of age group and the age was not influential in the performance of microhaematuria (King & Bertsch 2013).

As long as sex concerned, the performance of urine haemasticks was higher in males compared to females, This follows the same profile as the study done in Tanzania mainland where the performance of microhaematuria was higher in males compared to females due to high prevalence in males (Clements *et al*. 2008).

When status of praziquantel MDA considered as a factor, the urine dipstick was most sensitive and specific in those who taken praziquantel twice and least sensitive and specific in those taken praziquantel four and five times. The logistic regression analysis predicted that, age, sex and status of praziquantel MDA were factors that not associated with the false positive results and had influence on the performance of urine dipstick ($p > 0.05$).

Multinomial logistic regression predicted significant correlation and intensity considered as a factor influencing the performance of urine dipstick and associated with false positive results of microhaematuria ($p < 0.001$).

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATIONS

5.1. Conclusion

Praziquantel Mass Drug Administration coverage has been shown to have an impact towards decreasing prevalence of Urinary Schistosomiasis as well as reducing infection intensities in the infected school children.

This study has shown that, infection intensity had influenced the performance of the diagnostic methods.

Despite low prevalence of urinary schistosomiasis in Uwandani Chakechake district, urine dipsticks has been shown to be highly performing test for rapid screening of urinary schistosomiasis. The microhaematuria should be confirmed with gold standard (filtration for accurate diagnosis of the urinary schistosomiasis in the control programme in low prevalence areas after the praziquantel MDA has been performed.

5.2 Recommendations

- The study proposes that Urine dipsticks should be the recommended for initiating and monitoring mass treatment for *S. haematobium* in low and high prevalence areas but should be confirmed by filtration (microscopy) as gold standard.
- Prevalence has been lowered after six rounds of praziquantel MDA. Praziquantel is the key of schistosomiasis control. Further effort should be taken to magnify the coverage of PMDA to other schistosomiasis endemic districts all over Tanzania and then impact evaluations should be done after each round of MDA in the relevant areas.
- NTD programmes related to schistosomiasis control should be strengthened through funding and more researches should be done to ensure the pre-elimination of schistosomiasis in Uwandani and other parts of Zanzibar and Tanzania are reached that will lead us to the point of elimination.
- Those pupils observed microscopic egg positive and treated with praziquantel should be monitored and screened and provided with education related to urinary schistosomiasis to avoid further spread of infections.

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APPENDICES

Appendix I: Consent form (English Version)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCIES (MUHAS)
DIRECTORATE OF RESEARCH AND PUBLICATIONS
INFORMED CONSENT FORM
ID NO ……

Introduction

Greetings! My name is **Suleiman Amani Makame**, a student from MUHAS doing a research with a title; **''Factors Influencing Performance Of Screening Methods For Urinary Schistosomiasis Among School Children In Uwandani Pemba, Zanzibar - Tanzania, 2017''**.

Purpose of this study

This study is proposed to assess the diagnostic performance of screening (indirect diagnostic) dipstick methods for urinary schistosomiasis after wide scale use of Praziquantel in a school based schistosomiasis morbidity control programme in Uwandani Chakechake District in Pemba Island Zanzibar – Tanzania. 'Results from this study will help me to write a thesis that required for master degree award as MSc TDC student for academic year 2016/2017

Participation

If you accept to participate in this study, you will be required to answer questions and to grant urine for diagnosis.

Benefits and Risks

The information you will provide may help us to know appropriate diagnostic tests for urinary schistosomiasis in your area, to know the magnitude of the urinary schistosomiasis after four rounds of Praziquantel MDA. Those who will be found infected will be treated accordingly

There is no harm to anyone who will voluntarily participate in the study

Confidentiality

Confidentiality will be assured through secrecy by the use of identification numbers; also only authorized person shall have access to the collected data.

Address

If you have any enquiry you may contact me by sending a letter with this address: **Suleiman Amani Makame, to MUHAS, P.O BOX 65015 Dar es Salaam**. If you have any question about your rights as a participant please contact**,** Chairman of the Science and Publications Committee, P.O.BOX 65001.Dar es Salaam.Tel:2150302-6, 2152489

Agreement part

I therefore request you to contribute in this study by feeling the questionnaire and then collect your urine sample

DO YOU AGREE YES: ..... NO: ..... for appropriate response)□ □(Put

I have read/listened the contents in this form. I agree to participate in this study

Participant Signature..... Date.....

Research Assistant Signature..... Date.....

Appendix II: Informed Consent Form (Swahili Version)

CHUO KIKUU CHA SAYANSI ZA TIBA NA AFYA MUHIMBILI KURUGENZI YA UTAFITI NA MACHAPISHO

FOMU YA RIDHAA

Ridhaa ya kushiriki katika utafiti

Namba ya Fomu ……..

Utambulisho

Habari! Jina langu ni: Suleiman Amani Makame, ni mwanafunzi wa Chuo Kikuu MuhimbiliI nikisomea shahada ya uzamili katika fani ya magonjwa ya ukanda wa joto. Ninafanya utafiti kama sehemu ya masomo yangu kuhusu ― Vyanzo Vinavyoathiri Ufanisi katika vipimo vitumikavyo kwa ajili kupima kichocho cha mkojo kwa wanafunzi wa shule za msingi Uwandani wilayani Chakechake baada ya kupatiwa dawa kwa vipindi vinne”

Kusudi la utafiti

Utafiti huu unakusudia kufanya tathmini ya vipimo vitumikavyo kwa ajili ya kupima kichocho cha mkojo baada ya kupatiwa dawa kwa vipindi vinne.

Ushiriki

Ukikubali kushiriki katika utafiti huu kwa hiari, utapewa karatasi ya maswali utakayoyajibu pia utapewa kifaa/chombo kwa ajili ya kuweka sampuli ya mkojo.

Faida na hasara

Taarifa zitakazotokana na utafiti huu zitasaidia kunyambua kipimo sahihi kwa ajili ya kichocho cha mkojo, pia kugundua ukubwa wa tatizo hili la kichocho cha mkojo katika kijiji cha Uwandani baada ya kupatiwa dawa kwa zaidi ya vipindi vinne. Wote watakaokutwa na tatizo watatibiwa ipasavyo.

Zoezi hili halina tatizo kwa mshiriki.

Usiri

Usiri utazingatiwa kwa kutotumia majina, washiriki watapewa namba, na ni wahusika tu ndio wataweza kuwa na ukaribu na takwimu zitakazokusanywa

Mawasiliano

Endapo utakuwa na swali lolote kuhusu utafiti huu wasiliana nami kwa kutumia anwani ifuatayo; Suleiman Amani Makame, MUHAS, S.L.P 65015 Dar es Salaam. Endapo una swali lolote kuhusu haki zako kama mshiriki katika utafiti huu, wasiliana na Mwenyekiti wa Utafiti na Machapisho, P.O.BOX 65001. Dar es Salaam.Tel:2150302-6 2152489.

Kipengele cha Makubaliano

Baada ya maelezo hapo juu, nakuomba sasa ukubali kushiriki katika utafiti wangu, kwa kujibu maswali na kunipatia sampuli ya mkojo.

Je unakubali kushiriki?

NDIYO: ..... HAPANA: ..... kwenye sehemu husika)□□(Weka

Mimi nimesoma/nimesomewa na kuyaelewa maelezo yaliyomo katika fomu hii. Ninakubali kushiriki katika utafiti huu

Sahihi ya mshiriki..... Tarehe.....

Sahihi ya mtafiti msaidizi..... Tarehe.....

Appendix III: Structured Questionnaire (English Version)

Serial No----------

Structured questionnaire for primary school children to evaluate the performance of different diagnostic techniques for urinary schistosomiasis

Part A: Demographic information

Date of Interview _____

Name of school _____

Class _____

Age _____

Sex _____

Part B: To assess self reported urinary schistosomiasis symptoms

1. Do you currently pass or previously passed blood in urine?

i. Yes

ii. No

2. When does the urine come with blood?
i. With last few drops of urine?
ii. From the first to the last drop of urine

3. Do you feel pain during micturition?
i. Yes
ii. No

4. How often do you go to urinate per day?
i. Three times
ii. Four times
iii. Many times

5. How many times you taken praziquantel during annual school mass drug distributions?
i. Only once

ii. Two times
iii. Three times
iv. Four times
v. Never taken

Thank you

Appendix III: Structured Questionnaire (Swahili Version)

Nambari ya dodoso ----------

DODOSO KUHUSU KUENEA KWA UGONJWA WA KICHOCHO KWA WANAFUNZI WA SHULE YA MSINGI SHEHIA YA UWANDANI CHAKE PEMBA

Sehemu A: Taarifa binafsi za mhojiwa

Tarehe: _____

Jina la Shule _____

Darasa _____

Umri _____

Jinsia _____

Part B: Ripoti ya kuwepo kwa ugonjwa wa kichocho

1. Je unakojoa au uliwahi kukojoa damu?

i. Ndio

ii. Hapana

2. Wakati gani mkojo unatokana damu?

i. Mwisho

ii. Mwanzo

3. Jee unapata maumivu wakati wa kukojoa?

i. Ndio

ii. Hapana

4. Unakojoa mara ngapi kwa siku?

i. Mara tatu

ii. Mara nne

iii. Zaidi ya mara nne

5. Mara ngapi imewahi kupata na kutumia dawa za minyoo ya kichocho?

i. Mara moja tu.

ii. Mara mbili

iii. Mara tatu

iv. Mara nne

v. Mara tano

vi. Sjawahi kupata wala kutumia dawa.

Asante

Appendix IV: URINE ANALYSIS FORM

Personal Data.

ID Number…….School (or village), Date……./……./……..

Name ……Age……years……. Sex M….. F……

<table>
<tr><td colspan="2">A. Urine visual examination</td><td colspan="4">Present</td></tr>
<tr><td colspan="2">Visible hematuria</td><td>NO</td><td colspan="3">YES</td></tr>
<tr><td rowspan="2">B. Urine examination by microscope</td><td rowspan="2">Eggs/10mls of urine</td><td colspan="2">Heavy intensity threshold</td><td colspan="2">Heavy intensity infection</td></tr>
<tr><td>YES</td><td>NO</td><td>YES</td><td>NO</td></tr>
<tr><td>Schistosoma haematobium (filtration)</td><td></td><td></td><td>>50eggs/10mls of urine</td><td></td><td></td></tr>
</table>

Name of the investigator…….

Signature…….. Date……

Appendix V: Muhimbili Ethical Clearance letter

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

P.O. Box 65001
DAR ES SALAAM
TANZANIA
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Direct Line: +255-22-2151378
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E-mail: dpgs@muhas.ac.tz

Ref. No. MU/ PGS/SAEC/Vol.IX/ 5th June, 2017

Mr. Suleiman Amani Makame
MSc. Tropical Diseases Control
MUHAS.

RE: APPROVAL OF ETHICAL CLEARANCE FOR A STUDY TITLED: "FACTORS INFLUENCING THE PERFORMANCE OF SCREENING METHODS FOR URINARY SCHISTOSOMIASIS AMONG PRIMARY SCHOOL CHILDRENN IN UWANDANI PEMBE ZANZIBAR-TANZANIA"

Reference is made to the above heading.

I am pleased to inform you that, the Chairman has, on behalf of the Senate, approved ethical clearance for the above-mentioned study. Hence you may proceed with the planned study.

The ethical clearance is valid for one year only, from 2nd June, 2017 to 1st June, 2018. In case you do not complete data analysis and dissertation report writing by 1st June 2018, you will have to apply for renewal of ethical clearance prior to the expiry date.

Dr. E. Balandya
DEPUTY DIRECTOR OF POSTGRADUATE STUDIES

cc: Director of Research and Publications
cc: Dean, School of Public Health and Social Sciences

Appendix VI: Zanzibar Ethical Clearance Letter

SERIKALI YA MAPINDUZI - ZANZIBAR
ZANZIBAR REVOLUTIONARY GOVERNMENT
WIZARA YA AFYA
MINISTRY OF HEALTH

BARAZA LA UTAFITI, WAU
TEL: 3105750
FAX: +255 24 32561
TELEGRAM: HEALTHMIN

MOH RESEARCH COUNCIL
P.O. Box 236
ZANZIBAR

ETHICAL CLEARANCE LETTER

PROTOCOL NUMBER: ST /0003/MAY/017 **DATE:22 MAY, 2017.**

SULEIMAN AMANI MAKAME
STUDENT RESEARCHER

PROTOCOL TITLE **"Factors Influencing Performance of screening methods for Urinary Schistososmiasis among School children in Uwandani Shehia, Pemba."**

RE: ETHICAL CLEARANCE FOR CONDUCTING MEDICAL RESEARCH IN ZANZIBAR.

This is to certify that the research protocol entitled **"Factors Influencing Performance of screening methods for Urinary Schistososmiasis among School children in Uwandani Shehia, Pemba."** was received and reviewed by the Zanzibar Medical Research and Ethics Committee on May, 2017.

We would like to inform you that the decision of the committee to this protocol was "**Approved**".

The permission to undertake data collection is for one year beginning from the date of this letter.

The principal investigators have to provide progress report after six months and final report to the Ministry of Health and the Zanzibar Medical Research and Ethics committee ZAMREC.

Seek permission to publish from ZAMREC.

Any change made to the protocol need to be submitted to the committee for approval prior to its implementation

Thanks in advance,

DR. MSAFIRI MARIJANI
SECRETARY
ZAMREC
ZANZIBAR