School of Public Health

Adherence of Community Health Volunteers to Mass Drug Administration Guidelines for Schistosomiasis Control in Western Kenya

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DECLARATION

I, Charity Warigia Hungu, declare that this research report is my own, unaided work. It is being submitted for the Degree of Epidemiology in Implementation Science at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

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(Signature of candidate)

Date: 9th day of October 2019

DEDICATION

I dedicate this report to my Heavenly Father who has been a constant source of strength and comfort.

ABSTRACT

Background

Mass drug administration (MDA) of Praziquantel to at-risk populations is the main control strategy in endemic regions against Schistosomiasis. Community health volunteers (CHVs) are the primary implementers of MDA programmes for various neglected tropical diseases in sub-Saharan Africa and are key to achieving programmes goals. CHVs involvement in MDA activities is critical when assessing intervention implementation because of their connection with the health systems, programme managers, and the communities they work in. The objectives of this study were to measure adherence of CHVs to MDA guidelines and to determine the relationship between measured adherence and its determinants.

Methodology

A cross-sectional survey was conducted in Kisumu, Siaya and Homa Bay counties. The study population was comprised of 72 CHVs who were previously involved in MDA activities in western Kenya. Data was collected using validated interviewer-administered questionnaires and analysed using Stata v.14. The questionnaire was developed based on Carroll's conceptual framework for implementation fidelity and the current MDA guidelines for schistosomiasis. The outcome variable was adherence. Adherence scores were computed as an overall composite score derived by aggregating and averaging scores from two components of adherence, coverage and content. Logistic regression analyses were then applied to establish the determinants associated with adherence.

Results

More female CHVs (54/72, 75%) participated in the MDA activities compared to the male CHVs. The CHVs ages ranged from 27 to 67 years. Content and coverage were both delivered with high adherence to the guidelines by the CHVs, content was however shown to be an important component with regard to adherence as a higher number of CHVs recorded the

highest possible score in this component of adherence. In the three counties, 81% of the CHVs scored high adherence to the MDA guidelines. Quality of delivery was associated with high adherence. The odds of adherence were significantly higher for the CHVs who waited for side effects in the community members compared to those who did not wait (OR 4.05, 95% CI:1.05-15.59) and was statistically significant (p = 0.04).

Conclusions and Recommendations

It is important that programme managers monitor the process of implementation where CHVs are involved to ensure that programmes are implemented as intended. During the MDA activities, CHVs should be encouraged to wait after administration of treatment not only to manage the side effects but to also ensure that all community members are taking the medication and thus achieve the 75% treatment goal.

The current conceptual framework by Carroll provides a guide in the evaluation of CHV performance during intervention activities. Further research on adherence with regard to evaluating CHV performance would prove useful in ensuring programme goals are met.

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TABLE OF CONTENTS

LIST OF FIGURES

CHAPTER ONE

CHAPTER THREE

LIST OF TABLES

CHAPTER ONE

CHAPTER THREE

NOMENCLATURE

CDD: Community Drug Distributors

CHV: Community Health Volunteer

CHW: Community Health Worker

GAHI: Global Atlas of Helminth Infections

KEMRI: Kenya Medical Research Institute

LF: Lymphatic Filariasis

MDA: Mass Drug Administration

MUERC: Maseno University Ethics Research Committee

NACOSTI: National Commission for Science, Technology and Innovation

NTD: Neglected Tropical Disease

REDCap: Research Electronic Data Capture

S. haematobium: *Schistosoma haematobium*

S. mansoni: *Schistosoma mansoni*

SAC: School-age children

SBT: School-based treatment

SCORE: Schistosomiasis Consortium for Operational Research and Evaluation

STH: Soil-Transmitted Helminths

TDR: Tropical Disease Research

WASH: Water, Sanitation and Hygiene

WHO: World Health Organization

CHAPTER ONE - INTRODUCTION

1.1 GENERAL INTRODUCTION

Schistosomiasis is a neglected tropical disease (NTD) that occurs in tropic and subtropical regions globally including Africa, Asia and Latin America (1). Ninety per cent of global infections occur in sub-Saharan Africa mainly in rural areas (2). Schistosomiasis is the second most common parasitic disease after malaria and is the deadliest of all the NTDs; it kills an estimated 280,000 people annually in Africa alone (3).

It is estimated that nearly 120 million individuals from sub-Saharan Africa have schistosomiasis-related symptoms while 20 million others suffer morbidity from chronic symptoms of the disease (4). In Kenya, two of these schistosoma species are of public health concern, i.e. *Schistosoma haematobium*, which causes urogenital schistosomiasis and *S. mansoni*, which causes intestinal schistosomiasis (5).

The estimated prevalence rates of Schistosomiasis in Kenya are as indicated in figure 1.1 (6), with the highest prevalence recorded at 50%, in the coastal and western regions. Utilising geographic indicators, climatic and environmental data can help identify the areas with high transmission rates of schistosomiasis which is useful for intervention designers to focus their resources (7).

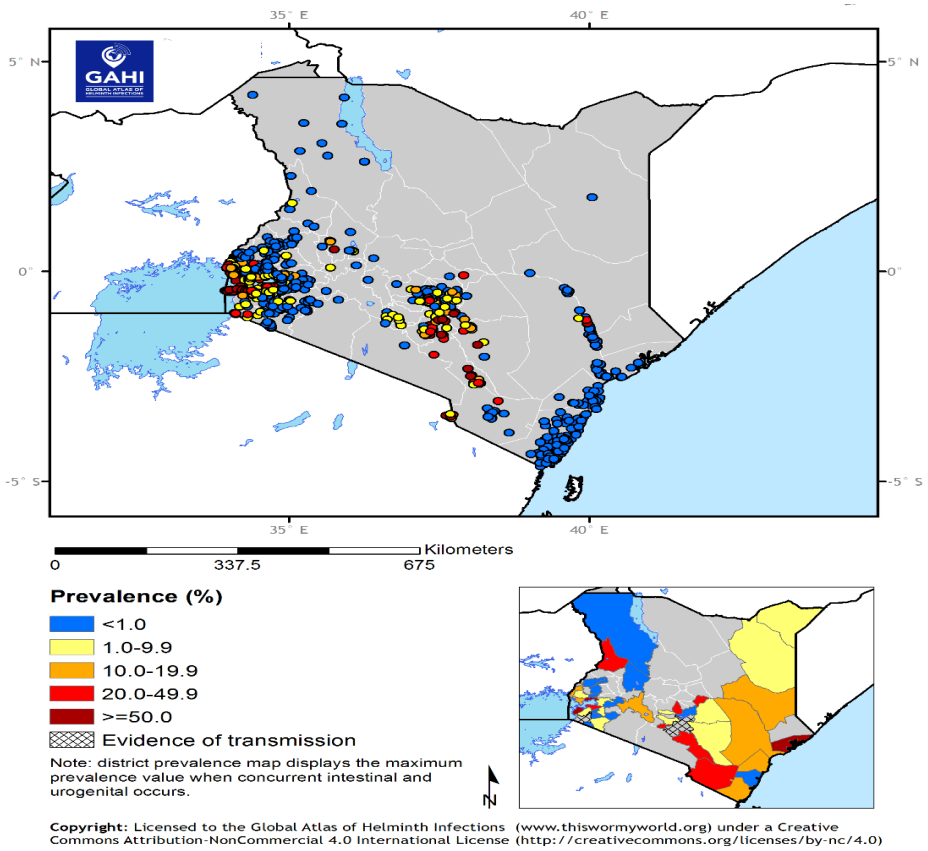

Figure 1.1 Map of Kenya showing prevalence of *S.mansoni* infection

Programmes to control Schistosomiasis depend on mass delivery of anti-helminthic drugs to school-age children (SAC) during school days also commonly referred to as school-based treatment (SBT). This is because SAC record a higher prevalence of soil-transmitted helminths and Schistosoma infections than any other age group (8).

School-based treatment provides infrastructure within which such interventions can operate successfully by reducing logistical challenges and thus lowering the programme costs (9). The main challenge with this intervention is that it does not reach the whole community, often missing children who are not in school and adults who may be infected with Schistosomiasis (8).

To address this challenge, a community based intervention which involves treating the whole community, such as mass drug administration (MDA), has been implemented and has proven successful in other parts of the region targeted at other NTDs for example, Onchocerciasis in Uganda (10) and Lymphatic Filariasis (LF) in coastal Kenya (11).

The MDA programme utilises the existing primary health care infrastructure where community members are recruited as drug distributors and are commonly referred to community health volunteers (CHVs) (8). Globally CHVs have been shown to play an important role in MDA exercises mainly where NTDs are prevalent in sub-Saharan Africa and parts of Asia (12). Apart from NTDs, CHVs also participate in health promotion activities within the health system, such as HIV/AIDS programmes, nutrition, vaccinations and distribution of health-related material (13).

To address challenges related to control and elimination of Schistosomiasis in African countries, the Schistosomiasis Consortium for Operational Research and Evaluation (SCORE), a large-scale multi-country project was established in various countries including Kenya in 2008. The project was run for 5 years with different treatment arms with an aim to understand the impact of the intervention in prevalence and intensity of Schistosomiasis (14).

In Kenya, the project was piloted in 2011 and complemented the school-based treatment, where it involved community-wide treatment in areas along the shores of Lake Victoria in Kenya with a prevalence of $\geq$ 25% of schistosomiasis in a moderate risk community (14). Briefly, the study had six arms each comprising of 25 communities or villages. The communities were provided with various combinations of school-based treatment (SBT) and holidays (no drugs were given) over a four-year period.

Communities in arm 1 received annual community-wide treatment (CWT) for four years; communities in arm 2 received CWT in the first two years, followed by SBT in years three and four; communities in arm 3 received CWT in the first two years, followed by 'holiday'. In the SBT, arm 4 received annual SBT for four years; arm 5 received SBT in the first two years, followed by 'holiday' in the last two years; arm 6 received SBT in years 1 and 3, alternated by 'holidays' in years 2 and 4 (15).

In summary, a total of 150 villages participated in the 5-year study, 75 of these villages were community-wide treatment and each village was assigned one CHV, thus 75 CHVs were involved in the community study (15). Community health volunteers were enrolled from the community by public health officials and were involved in the intervention activities, that is, drug distribution and health education to the community members (8).

Training for the MDA exercise was done by the programme officials from the Kenya Medical Research Institute (KEMRI) and focused on schistosomiasis and community mobilisation, household enumeration, guidelines on duration of treatment, correct dosage based on the dosing pole and management of side effects. The training covered topics such as how to identify and report issues encountered during the distribution and coverage reporting (16).

Guidelines used for MDA by the CHVs were adapted from the Ministry of Health's national school-based deworming teacher training manuals and were edited by the programme officials to suit the programme's needs (16). The role of the CHVs as outlined in the guideline was to educate the community about the MDA activities, distribute tablets and record treatment.

Briefly, the CHVs were to sensitize the community members about the intervention by using posters, handing out materials with information on worms and door to door sensitisation (17). The CHVs were to directly observe that the household members swallowed the tablets during the administration of treatment. The treatment booklets and surplus tablets were to be returned to the community health assistant to whom the CHVs were to report to directly at the end of the day's activities (See Appendix XIII) (17).

The outcome of the SCORE study indicated that the overall prevalence and intensity of schistosomiasis reduced over the intervention period. The authors suggest that continued monitoring of programme data needs to be considered for change of strategy in areas with reduced MDA effectiveness (15). The use of CHVs as drug distributors in the community produced improved results with regard to the treatment coverage as more of the community members were treated compared to the school-based treatment alone (8).

The conceptual model for Implementation fidelity by Carroll et al. (18) provides a mechanism for assessing the effectiveness of the individual components of the MDA activities tasked to the CHVs to help identify what is essential to successful implementation of this intervention. This study aims to identify some of the determinants contributing to or preventing the successful implementation of the programme in the real-world setting.

1.2 Problem statement

Western Kenya records the highest prevalence of *Shistosoma spp.* infection in Kenya, which is associated with activities near Lake Victoria (19). Access to treatment for schistosomiasis has been made available over the years in countries where communities face significant morbidity due to infection with schistosomiasis (9,20,21).

Seventy-five per cent (75%) of the population at risk still do not receive Praziquantel treatment (20,22) despite this treatment being freely available in high and moderate risk communities (8). Results from various studies suggest that there is a huge gap between ideal practice and the actual performance of health care professionals in application of guidelines (23).

A study to assess CHV performance in control of NTDs in Uganda found that treatment coverage reports by the CHVs were overestimated (12). Mwinzi et. al., 2012 revealed in their study that even though CHV records indicated high treatment coverage, this information was only based on the compounds that had been visited and not the total target population (24). This implies that CHV records of coverage are not reliable and that close monitoring of intervention activities is required.

It is therefore important to understand CHV fidelity to the intervention guidelines to enable programme managers to evaluate the quality of implementation and factors associated with intervention outcomes.

1.3 Justification

The involvement of the CHVs in MDA interventions for NTDs enables programme managers to gain useful feedback from the communities and understand challenges that arise during implementation and to monitor interventions progress (16). There are studies that describe the experiences and perspectives of CHVs who are involved in MDA activities within the SCORE project (8,16), however, these studies did not evaluate CHVs adherence to the MDA guidelines.

The findings from this study will provide more insight to the programme managers and researchers in organising future MDA exercises and influence programme activities to ensure that CHVs performance can be evaluated thus improve the intervention outcome and ultimately the health outcomes of the population.

1.4 Aim

To measure adherence of community health volunteers (CHVs) to the MDA guideline for schistosomiasis and to identify the determinants of adherence to the MDA programme in western Kenya.

1.5 Objectives

1) To measure adherence of community health volunteers to MDA guidelines
2) To determine the relationship between measured adherence and the determinants of adherence

1.6 Literature review

Schistosomiasis is an NTD that is endemic in 56 districts in Kenya with the highest prevalence occurring in the lower eastern and lake regions as well as in irrigated schemes such as Mwea in central Kenya (25). The presence of water bodies such as lakes and rivers favour the life cycle of the parasite and allows for continued transmission throughout the year (26).

The infective stage of the parasite penetrates the skin of the human host who is exposed to infected water when swimming, bathing or washing (27). Morbidity in adults causes reduced productivity at work while in children Schistosomiasis causes under-nutrition, anaemia, stunting and cognitive impairment (19).

1.6.1 Interventions to control schistosomiasis

The main interventions used to control Schistosomiasis include improved sanitation, health education, snail control and mass drug treatment using Praziquantel (1,28). Efforts by several organizations have led to the increased awareness and support of interventions towards Schistosomiasis control (29). These efforts are expected to result in elimination or eradication by the year 2020 in line with the targets set by the WHO NTD roadmap (30).

1.6.1.1 Improved sanitation

Areas endemic to Schistosomiasis have been associated with inadequate sanitation and lower standards of living (24). Access to safe water supply, proper sanitation infrastructure and promotion of hygiene, such as bathing, hand-washing and storage of water for home use, are all critical to reduce exposure to infection with Schistosomiasis (31).

Interventions that include water, sanitation and hygiene (WASH) are highly effective at reducing prevalence of Schistosomiasis by up to 77% (31). However, access to clean water and sanitation remains a challenge as was demonstrated in a socio-economic survey by Mwinzi et al. in east Uyoma location in western Kenya, whereby only 36% of the respondents had access to piped water while 30% did not have access to a sanitation facility and used the open ground for defecation (24). The high cost of implementing and maintaining water and sanitation systems in rural areas is a major deterrent to efforts to reduce urine and faecal contamination of water (28).

1.6.1.2 Snail control

Freshwater snails of the genus *Biomphalaria* are the intermediate hosts of the infective fluke larvae of the genus *Schistosoma* (32). An effective approach in elimination of snail population has been the seasonal use of molluscicides (application of chemical compounds) which targets the snail's transmission cycle, however there are concerns about environmental pollution and an imbalance in the ecosystem brought about by their toxic effect on organisms in the environment (20,33). Environmental methods such as burying the snail's habitats, drowning the snails or creating drainage tunnels have been successfully used as alternatives to molluscicides (33).

1.6.1.3 Health education

Health education increases the communities co-operation with intervention programmes (20) and this includes sensitising the community on the benefits of the intervention, side effects of treatment and how to prevent schistosomiasis in the community (16). Research indicates that the implementation of health education resulted in an overall decrease of Schistosomiasis by 6% and an increase of Schistosomiasis-related knowledge by up to 51% (34).

1.6.1.4 Mass drug administration

Mass drug administration of treatment to at-risk populations is the cornerstone of control strategies in endemic regions and is the most widely used intervention against schistosomiasis (20). Individuals in endemic communities are targeted and treated regardless of their infection status (14,35).

Guidelines provided by WHO indicate that mass treatment with Praziquantel should be targeted at high-risk groups and at least 75% coverage should be achieved (36). The high-risk groups include school-age children and adults considered to be at risk such as, pregnant and lactating women; individuals who have contact with infected water, like farmers, irrigation workers, fishermen, and women performing domestic chores, to entire communities living in endemic areas (35).

The benefits of administering Praziquantel include high efficacy, safety, ease of administration and mild to moderate side effects. The WHO guidelines for MDA recommends community-wide treatment to be conducted annually or bi-annually during the primary school year depending on the community's risk category. In moderate-risk communities where the prevalence of schistosomiasis is greater than or equal to 10% and less than 50% treatment is done once every two years for school-age children and only to adults considered to be at risk (22).

1.6.2 Role of Community Health Volunteers in Mass Drug Administration

The community health workers (CHWs) are referred to by various terms including community drug distributor or community resource person, community health volunteer, village health worker, health promoter, community health agent etc. in different regions of the world (37). For the purpose of this study, the term community health volunteer will be used to refer to community health workers.

1.6.3 Selection of CHVs

All the above-mentioned CHVs carry out health-related care delivery and are trained for the work they perform in the community. The CHVs are selected by community members during community meetings where they reside and are supported by the health system but are not necessarily employed by it, they also have shorter training compared to health professional workers (37).

Most NTD interventions rely on community-directed MDA due to weak or absent health system infrastructure (38). In most African settings, for example, in Uganda, there is a shortage of health workers and only less than 50% of the population live in close proximity to a health facility. This has led to the delegation of tasks from qualified health workers to less specialised health volunteers to bridge this gap (12). CHVs are then the primary implementers of MDA programmes for various NTDs in sub-Saharan Africa and are key to achieving programmes goals (12).

In India, MDA targeting LF shows that CHVs are able to effectively reach members of the community where they are responsible for sharing information before MDA activities, they have also been shown to improve community compliance with the treatment (39). Similarly,

in Indonesia, CHVs are specifically responsible for three main MDA activities for LF, which are health education prior to MDA, distribution of drugs and reporting of MDA activities (40).

1.6.4 Factors that influence CHV performance

It has been suggested that factors such as socio-demographic factors, motivation, skill, organisational input such as training and supervision and knowledge of programme activities influence CHV performance (41).

CHVs administering Praziquantel for schistosomiasis control during a mass drug exercise in western Kenya reported that they were committed and driven by a desire to serve their community. They also indicated that they adhered to their training guidelines and directly observed treatments to ensure drug compliance by community members (8).

In a study to compare treatment coverage of LF by health system and community-directed treatment in Kenya, treatment coverage was shown to be significantly higher when administered by CHVs who went door to door compared to the health system where drugs were given from a central point (11).

1.6.5 Challenges experienced by CHVs during MDA activities

Certain challenges with MDA have been reported by the CHVs which include poor drug delivery strategies, limited number of CHVs, motivation of CHVs through training and incentives among others (42). Other challenges encountered include poor treatment campaigns during intervention activities and lack of compliance with treatment by the community members (20).

In a study to understand the knowledge and attitudes of CHVs to onchocerciasis in North West Ethiopia, only 11% of the CHVs knew the cause of onchocerciasis, while only 24% and 22% had poor attitude and practice about onchocerciasis respectively. The authors of the study suggest that this poor knowledge, practice and attitudes could be due to poor training and lack of supervision of CHVs in delivering health education which could affect the success of this programme (43).

Some challenges noted from a study in Uganda included lack of incentives, time allocated to perform their duties and time spent collecting drugs from the health facility. The study concluded that due to the lack of feedback on CHVs performance, programme coverage was not achieved and thus morbidity control and elimination goals for 2020 were not likely to be reached (12).

The national programme to eliminate LF in India noted that some of the issues related to non-compliance included lack of adequate training of the CHVs and the absence of follow-up after MDA. The CHVs also discussed some of the operational difficulties they faced such as lack of medicine to treat side effects of the drug, delay in receiving funds to conduct MDA and supervisors non-performance (44).

In a review of factors that affect individual's compliance with MDA for LF, drug distributors identity was shown to be important, training of staff delivering MDA, their motivation and drug distributor use of directly observed treatment. The authors acknowledge that those delivering the MDA need to be known and trusted by the community, be knowledgeable about the disease, be motivated and convinced about the importance of the programme as well as have time for the MDA and be willing to engage with the community (39).

The focus now is on how to improve MDA activities and make them effective to achieve the programme goals (20), to ensure this, evaluation of programme activities and giving feedback to the programme designers is fundamental (45).

1.6.6 Evaluation of CHV performance

Evaluation of CHV performance during interventions is important to understand how well or poorly they are performing and to target efforts so as to improve their performance (46). In a study to evaluate CHV performance of NTD's in Uganda, CHV treatment registers were retrospectively assessed for accuracy of treatment coverage they recorded, however, the information was inaccurate by more than 12% with majority of these being overestimations (12).

O'Brien and colleagues describe a four-step role-outcomes linkages evaluation (ROLE) model that demonstrates the importance of selection, training and role enactment of CHVs and the outcomes of the intervention. The authors emphasise that a clear understanding of the CHV roles greatly assists in the evaluation of CHV programmes and the use of the conceptual model provides a guide for the selection and training of CHWs in intervention studies (45).

Similarly, this study employed a conceptual framework for implementation fidelity by Carroll et al. (18) to describe the various elements that can be measured to ascertain that adherence to the Schistosomiasis guideline by CHVs is of the highest standard by evaluating CHV performance.

1.6.6.1 Conceptual framework for implementation fidelity

The conceptual framework for implementation fidelity provides a mechanism to assess the effectiveness of individual components of adherence and the relationship to these components to identify what is essential to successful implementation of an intervention in order to guide in programme planning (18,47). The principal component in the framework is fidelity, which in treatment delivery can be further described as provider adherence (18).

Adherence can be defined within four sub-categories, namely, content, coverage, duration and frequency. Content can be described as the main ingredient that the intervention seeks to deliver, coverage refers to the proportion of individuals exposed to the intervention as intended. Frequency and duration describe how regularly and how long the individuals are exposed to the intervention respectively. If an intervention adheres completely to the content, frequency, duration and coverage as designed, then adherence is presumed to be high (18).

The determinants associated with adherence include complexity of intervention, quality of delivery, strategies to facilitate implementation and participant responsiveness (18), these determinants influence adherence to guidelines and ultimately the success of the intervention (48).

Figure 1.2 shows the components of adherence and the determinants associated with adherence. The framework has been adapted from Carroll et.al., 2007 (see Appendix V).

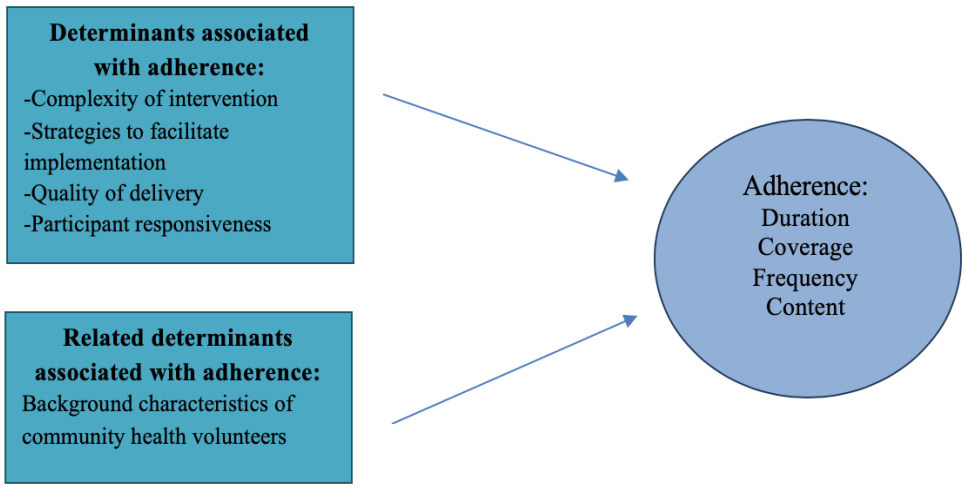

Figure 1.2 Conceptual framework showing factors associated with adherence in community health volunteers adapted from Carroll's framework for implementation fidelity (18)

Intervention complexity is the description of an intervention guideline that is either simple to follow, complex to understand, detailed or vague in terminology (18). For instance, a study looking at determinants of adherence by health professionals showed that aspects of guideline recommendations which were clear and simple to follow facilitated implementation, while other aspects that were complicated, unclear or too lengthy hindered their implementation (49).

Quality of delivery is concerned with the delivery of an intervention in a manner that will achieve the intended outcome. Competing demands for health care professionals time can reduce their commitment and motivation and effectiveness in delivering the intervention (18), therefore reducing the quality with which an intervention is delivered. Providing ongoing

monitoring and feedback to those delivering an intervention demonstrates the importance of quality of delivery and its effect on the outcome on adherence (18).

Facilitation strategies ensure that everyone administering the intervention receives the same training and support with the aim of quality delivery and uniformity. Support includes the provision of materials for the intervention, guidelines, training and support from their supervisors (18). The role of facilitation is important to ensure that variations that occur in complex interventions are dealt with and adherence is optimised, this however does not mean that more facilitation leads to better implementation (18).

Participant responsiveness measures how participants of an intervention respond to or engage with the intervention components. If participants find no relevance of the intervention then adherence will ultimately be recorded as low (18).

Participants are not just those who receive the interventions but also those who are responsible for delivery. If those delivering an intervention are eager, then those receiving the intervention will respond and high levels of adherence will be achieved (18). From a patient's point of view, if treatment is acceptable, patients are more likely to adhere to treatment and to benefit from improved clinical outcomes (50).

Related determinants associated with adherence in this study include socio-demographic and socio-economic characteristics of CHVs. Many users of research evidence, for example, programme managers and implementers, face unique pressures and constraints (51).

1.6.6.2 Importance of guidelines in health care and the outcome on adherence

The use of guidelines ensures uniformity and quality provision of health care (52), their use is certainly complex and adherence is usually influenced by multiple factors which include the user's unawareness of guidelines, guideline complexity, disagreement with guidelines and applicability to daily routine (52). Effective guidelines are those that are followed in practice (53), for example, studies have shown that evidence-based recommendations are better followed than those that lack scientific evidence (18,47,54).

In a study by Burgers et al., 2003, four attributes of guidelines were associated with high adherence rates while eight attributes had a negative effect on adherence. Some facilitators discussed in the study included; scientific soundness, discussion of benefits and harm to the end-user, guidelines were easy to follow, effects were immediate, and the guideline was compatible with norms and values of the clinicians (53). Some barriers that were identified in this study included the need to acquire new knowledge and skills, demand for changes in organisation and routines and negative reactions in patients (53).

In a study by Nuwaha et al. CHVs cited non-payment of allowances which affected their motivation to carry out intervention activities, this in turn affected the adherence of the community members in taking the treatment (55).

Lugtenberg et.al. identified barriers that prevented general practitioners from adhering to guidelines, they included a lack of agreement with the guidelines, organisational constraints and lack of knowledge regarding guideline (56). Other factors that influence adherence include knowledge, previous experience and number of participants which all significantly influenced adherence of intervention delivery (57).

Adherence data have been described as the proportion of programme components that are delivered compared to the number prescribed. Studies report varying levels of adherence to guidelines from strict adherence to subtle or major changes to the guidelines (58). Currently, there is no standard measure for adherence, a scoring system based on available guidelines and protocol requirements is employed (52).

The conceptual framework for fidelity was selected for this study as the components of the framework are applicable to the context of the MDA guidelines and CHVs and can be used to measure adherence which will assist in understanding the aspects of the MDA guideline that contribute to the successful implementation of MDA in western Kenya.

Briefly, questions relating to each component of adherence, that is, content, duration, frequency and coverage were generated using the guideline to measure adherence (See appendix IV). Similarly, questions relating to the determinants associated with adherence were also generated from the guideline used for the MDA exercise as detailed in Table 1.1.

Table 1.1 Summary of the key components of the guideline associated with adherence

Determinant	**Questions relating to determinant**
Background characteristics of CHVs	Skills Confidence Motivation Socio-demographic factors, i.e., occupation, education, age, sex
Complexity of intervention	Ease of understanding guideline Comprehensiveness of guideline Familiarity with guideline content
Strategies to facilitate implementation	Supervisory support Promotional materials to support MDA activities Engagement with community Training
Quality of delivery	Treatment coverage Administration of praziquantel and direct observed treatment Follow-up visits Treatment records Side effects management Reporting of MDA activities
Participant responsiveness	Community engagement with MDA activities Community opinions about praziquantel

This framework will give an understanding of how the various determinants contribute to the successful implementation of the SCORE intervention in western Kenya. The framework is currently the most complete framework for implementation fidelity and has been extensively used to examine other health interventions (47,59).

CHAPTER TWO- METHODS

2.1 Introduction

This chapter describes the study design, study site and population, a brief description of the intervention is also given. Data collection and analysis is also described in detail and the ethics process is documented.

2.2 Study design

This was a cross-sectional study which collected primary data from CHVs on their use of guidelines provided for MDA in Western Kenya, based on Carroll's theoretical framework for implementation fidelity (18).

2.3 Study site

The study was conducted in three counties; Kisumu, Siaya and Homa Bay in Western Kenya which border Lake Victoria. Selection of the study site was based on the high prevalence of schistosomiasis and the pilot SCORE project which involved community-wide treatment.

The study region is predominantly inhabited by the Luo community. The region experiences modified equatorial climate with rainfall seasons and relatively high temperatures throughout the year. Subsistence farming and fishing are the main economic activities of the Luo community (60).

2.4 The intervention

The intervention activities included health education and administration of Praziquantel to community members. Intervention activities were carried out by CHVs who had previously participated in the SCORE MDA project as drug distributors.

These CHVs were recruited by public health officers from the Ministry of Public Health and Sanitation and worked closely with the project co-ordinators from the Kenya Medical Research Institute (KEMRI). No Praziquantel MDA activities had been conducted in these villages prior to 2011. Villages that recorded >25% prevalence of schistosomiasis were selected and randomised into one of six study arms.

2.5 Study population and sampling strategy

A total of 75 CHVs formed the study population. Each CHV administered the intervention in a village, thus, the distribution of the CHVs was as follows, 11 villages in Kisumu county, 37 villages in Siaya county and 27 villages in Homa Bay county. Only 72 CHVs were interviewed from the three counties as some of them could not be reached after the MDA exercise. There was thus no sample calculation, all available CHVs were conveniently included as participants in the study. The 72 CHVs were informed of the study in detail, invited to participate and gave their full consent in writing (see Appendix II and Appendix III).

2.6 Data collection and management

A questionnaire was designed using REDCap (Research Electronic Data Capture) v7.6.3 electronic data capture tools hosted at the University of the Witwatersrand. REDCap is a secure, web-based application for designing online surveys and databases for research purposes (61). The questionnaire was designed to capture components of adherence based on the framework by Carroll and the current training guidelines used by the CHVs (See Appendix V). The questionnaire contained 72 ‘Yes-No’ button and checkbox options addressing broad topics related to CHV guideline as indicated in Table 1.1.

For adherence components, summation of the questions answered correctly for coverage and content were used to score adherence for each of the CHVs. To score coverage, questions regarding treatment coverage by the CHVs were asked; while content was measured by activities the CHVs carried out with regard to creating awareness, surplus Praziquantel tablets directly observed treatment and recording of treatment.

In total, 11 items from coverage and content were used to score adherence. Frequency and duration were not included in the adherence score since these activities were not clearly defined by the programme designers.

Firstly, the questionnaire was validated by establishing face validity with the staff from KEMRI who were involved in the SCORE project. We then piloted the questionnaire with 11 CHVs from Kisumu who helped us identify ambiguous terms and questions. Minor modifications were done to improve the phrasing of some questions, for example, the CHVs referred to schistosomiasis as bilharzia. The responses from the pilot were included in the final research as they did not impact the validity of the questionnaire.

The questionnaire which was generated online, was printed out and distributed in hard copy and administered to the 72 CHVs by the investigator and two trained research assistants. Each CHV was given a unique identifier and no names were recorded on the questionnaire.

The CHVs responses were then captured on REDCap v7.6.3 by the investigator who reviewed each response for any issues; a data quality check on REDCap was run to check the data for discrepancies. The data was then exported as a .csv (comma-separated values) file to Stata v14.1

(StataCorp, Tx, USA) for data processing. Data cleaning on Stata was performed, including coding and renaming of variables to facilitate analysis.

2.7 Outcome variable and explanatory variables

The outcome variable was adherence; the score assigned to the variables that were used to construct adherence was summed to provide a total score for each respondent, four variables for coverage and seven variables for content as shown in Appendix IV.

A score of 1 was assigned where a question was answered correctly in line with the guideline and 0 was scored where a question was not answered according to the guideline. The total score for adherence thus ranged from 0 to 11. A score for each component was assigned to reflect the importance of the component on adherence measured. After calculating the median distribution of the score, the CHVs who scored higher than or equal to a median value of 80% were categorised as having high adherence whereas those who scored less than the median value were categorised as having low adherence.

Determinant variables were used to predict the value of adherence. Five groups of determinant variables were used: strategies to facilitate implementation, quality of delivery, complexity of intervention, participant responsiveness and background characteristics of the CHVs. Each group of determinants had several questions associated with them as described in Table 1.1 and detailed in the questionnaire (See Appendix IV).

2.8 Statistical analysis

The characteristics of all variables, outcome and determinants, was examined using contingency tables, specifically, Fisher's exact test was applied to determine the statistical significance of relationships among the selected variables due to the small sample size, most of the cell values had less than 5 observations. The level of significance was set at $p<0.05$.

Frequencies and proportions were used to describe the background characteristics of the CHVs, and the determinants associated with adherence in the three counties and overall. Logistic regression analyses were used to establish determinants associated with adherence. Each of the determinants was run against adherence score and variables with a probability value cut off point of 0.25 and below were selected to be included in the regression model (62).

The estimated measures of association were assessed using odds ratios (ORs). Bivariate regression analyses were employed to determine the relationship between adherence and each determinant. In the final analysis, crude ORs and 95% confidence intervals (CIs) were determined for all significant variables.

2.9 Ethics

This study protocol was reviewed and approved by the Human Research Ethics Committee of the University of the Witwatersrand, clearance certificate number M180147 (see Appendix VI) and the Maseno University Ethics Review Committee (MUERC) ref. MSU/DRPI/MUERC/00512/18 (see Appendix VII). Thereafter, permission was obtained from the government body, National Commission for Science Technology and Innovation (NACOSTI) ref. NACOSTI/P/18/17060/21685 (See Appendix VIII).

The county commissioners and county public health offices in each county were informed of the study. The purpose of the study and its objectives were explained to the community health volunteers in a language that they were comfortable with i.e. English, Kiswahili and Dholuo. Upon agreeing to participate, the CHVs were required to sign a written consent form acknowledging their participation and understanding of the study (see Appendix III). They were made aware that participation was free, and they could withdraw at any time from the study without being penalised or coerced to return to the study.

CHAPTER THREE- RESULTS

3.1 Introduction

In this chapter, the results of the study are presented with reference to the objectives of the study, which was to measure adherence of CHVs to MDA guidelines and to determine the relationship between the measured adherence and the determinants of adherence. The data are presented in graphs, tables and text.

3.2 Socio-demographic and socio-economic characteristics of the CHVs

All the 72 CHVs that were interviewed were from the Luo community and resided in the study area during the intervention activities.

More female (54/72, 75%) CHVs participated in the MDA activities compared to the male CHVs. The CHVs ages ranged from 27 years to 67 years. Of these, (56/72,78%) CHVs were married and the majority (38/72,53%) were women.

Most of the CHVs (51/72, 71%) reported that they had completed secondary education. The CHVs who reported to be non-salaried workers were 62/72, 86% of the CHVs.

The CHVs who conducted two or less MDAs were 42/72,58%, while those who had conducted more than 2 MDAs were 30/72, 42% CHVs. The mean number of MDAs that the CHVs had participated in was 2 while the maximum that they reported was 5.

Most (37/72, 51%) CHVs received support from other CHVs when conducting the MDA exercise. Some (23/37, 62%) CHVs who received support said they helped one another in mobilising the community for MDA, 6 CHVs said those who helped them had interest in the exercise and 3 CHVs said distance alone was unmanageable and they enjoyed working together. Those who did not receive support indicated that some of their colleagues were not trained to carry out that particular MDA (10 CHVs), some 6 CHVs said that they needed no help or that

the other CHVs wanted to be paid, 19 CHVs did not give a reason for their response (See Appendix XII).

Majority (68/72, 94%) of the CHVs indicated that they were motivated to follow the guidelines while (4/72, 6%) CHVs said they were not motivated to follow the guidelines.

Table 3.1 Sociodemographic characteristics of community health volunteers

Variable	**n (%)**	***Variable***	**n (%)**
Sex		***Number of MDA exercises conducted***	
Females	54 (75%)	*1-2*	42 (58%)
Males	18 (25%)	*>2*	30 (42%)
Age (years)		***Eligibility of community to take Praziquantel***	
25-44 years	33 (54%)	*Yes*	57 (79%)
>45	28 (46%)	*No*	15 (21%)
Education		***Motivation to follow guidelines***	
Primary school	21 (29%)	*Yes*	68 (94%)
Secondary school	51 (71%)	*No*	4 (6%)
Marital status		***Support from other CHVs to follow guidelines***	
Not Married	16 (22%)	*Yes*	37 (51%)
Married	56 (78%)	*No*	35 (49%)
Occupation			
Non-salaried worker	62 (86%)		
Salaried worker	10 (14%)		

3.3 Adherence

The CHVs recorded a high score on each of the components of adherence, content and coverage.

The lowest score recorded for content was 57% by 4 CHVs, while the highest was 100% by 47 CHVs as shown in Table 3.2. The CHVs also recorded high scores on coverage, most of them scored 75%, that is 39 CHVs while the lowest score was 25% by 5 CHVs in this group. Overall, the content was shown to be an important component with regard to adherence as a higher number of CHVs scored a maximum 7 out of 7.

Table 3.2 Score of the two components of adherence, coverage and content, among the community health volunteers

Coverage score (n/N,%)	**Number of CHVs (n)**	**Content score (n/N, %)**	**Number of CHVs (n)**
1/4 (25%)	5	4/7 (57%)	4
2/4 (50%)	17	5/7 (71%)	5
3/4 (75%)	39	6/7 (86%)	16
4/4 (100%)	11	7/7 (100%)	47
	72		72

Overall adherence scores were also reported across the three counties as shown in Table 3.3. Kisumu county had a mean score of 88% with a minimum score of 63% and a maximum score of 100%; Siaya county had a mean score of 82% with a minimum score of 45% and a maximum score of 100% whereas, Homa Bay county had a mean score of 86% with a minimum score of 45% and a maximum score of 100%. The difference in the adherence scores across the counties was not significant (p=0.42).

Table 2.3 Distribution of high and low adherence across the three counties

Adherence score	Kisumu	Siaya	Homa Bay	Overall n (%)
High n (%)	10	29	19	58 (81%)
Low n (%)	1	10	3	14 (19%)
Total	11	39	22	72 (100%)

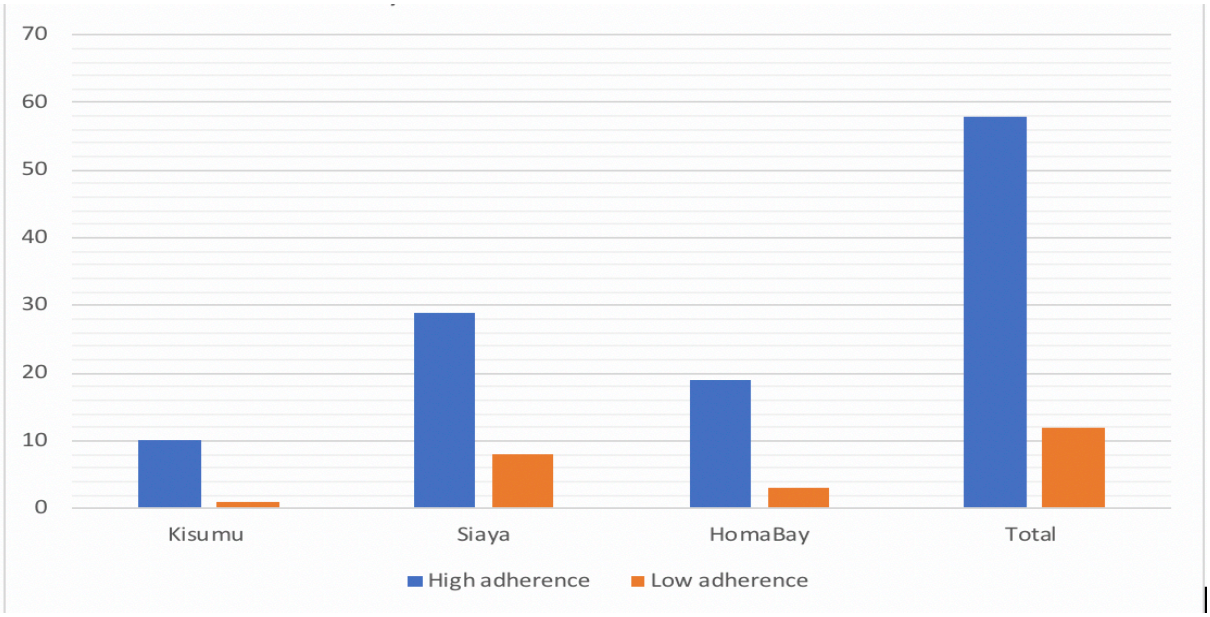

Figure 3.1 Bar chart showing high adherence and low adherence among the community health volunteers in Kisumu, Siaya and Homa Bay counties

3.4 Determinants of adherence to MDA guidelines for Schistosomiasis control by CHVs in three counties in Kenya

3.4.1 Complexity of intervention

The questions that focussed on the complexity component of the framework from the guideline included the CHV assessment of training they received and their understanding and familiarity of the intervention as shown in Table 3.4.

With regard to understanding the guideline, (66/72, 92%) CHVs reported that they understood the guideline and the rest of the CHVs did not completely understand it. Amongst those who scored high adherence, (55/72, 95%) CHVs understood the guidelines whilst the other (3/72, 5%) CHVs indicated they had not understood the guidelines.

The difference in adherence between the two groups was not statistically significant, however, the p-value 0.08 qualified to be included in the regression model.

The CHVs who said that the guideline was easy to understand constituted 86% (62/72), while (10/72, 14%) CHVs said it was hard to understand. The sections of the guideline that the CHVs felt were hard included the life cycle, signs and symptoms of schistosomiasis, treatment and side effects of the drugs and schistosomiasis control strategies.

Those CHVs who said that the guideline was detailed enough were (60/72, 83%), compared to (12/72, 17%) CHVs who said that the guideline was vague. The sections of the guideline that the CHVs reported were vague included, side effects of the drugs, use of treatment booklets during the MDA and the life cycle of schistosomiasis.

The CHVs indicated that they were somewhat familiar with the guidelines for MDA (16/72, 22%) CHVs compared to (56/72, 78%) CHVs who reported they were very familiar with the guidelines.

In total, 58/72, 81% CHVs scored high adherence whereby (44/72, 76%) CHVs were very familiar with the guidelines and (14/72, 24%) were somewhat familiar with the guidelines. The difference in adherence in the two groups was not statistically significant (p=0.72).

Regarding the skills required for MDA, (70/72, 98%) CHVs said that skills were required for conducting an MDA exercise, (2/72, 2%) of them said no skills were required. Among those who scored high adherence, (55/58, 95%) CHVs had the skills for MDA while (3/58, 5%) CHVs did not have the skills for MDA. The difference in adherence in the two groups was not statistically significant (p=0.54).

Table 3.4 Association of complexity of intervention guideline and adherence score

Complexity of intervention guideline

Variable	**N=72**	**Adherence**		**P-value**
	n (%)	**High**	**Low**	**(exact test)**
Comprehension of guideline				
Easy to understand	62 (86 %)	50 (86%)	12 (86%)	1.00
Hard to understand	10 (14%)	8 (14%)	2 (14%)	
Comprehensiveness of guideline				
Detailed	60 (83%)	49 (85%)	11 (79%)	0.69
Vague	12 (17%)	9 (15%)	3 (21%)	
Understanding of the guideline				
Yes	66 (92%)	55 (95%)	11 (79%)	0.08
No	6 (8%)	3 (5%)	3 (21%)	
Familiarity with the guidelines				
Very familiar	56 (78%)	44 (76%)	12 (86%)	0.72
Somewhat familiar	16 (22%)	14 (24%)	2 (14%)	

Necessary skills required to follow MDA guidelines				
Yes	66 (94%)	55 (95%)	11 (92%)	0.54
No	4 (6%)	3 (5%)	1 (8%)	

3.4.2 Strategies to facilitate implementation

This section focused on the availability of intervention materials for health education, treatment and supervisory support to enable the CHVs carry out the intervention activities as planned. The detailed results are presented in tabular format in Appendix IX.

All CHVs reported to have received a one-day training before the MDA exercise began. On the day of the MDA exercise, all CHVs reported having received Praziquantel tablets to administer to the community; (2/72,3%) CHVs indicated that they did not receive the treatment booklets and the dosing pole. Other items like t-shirts, bags and pens were also received by the CHVs (See Appendix XII).

The CHVs who indicated that they received supervisory support from the programme managers that is, the KEMRI staff who were organising the project activities during the intervention constituted (67/72,93%) CHVs, while (5/72,7%) CHVs indicated they were not given supervisory support.

Among those who scored high adherence, (54/58, 93%) CHVs were given supervisory support while (4/58, 7%) CHVs were not given supervisory support. The difference in adherence between the two groups was not statistically significant (p= 1.00).

CHVs who received supervisory support, rated the support as very helpful, (64/67, 96%), while the other CHVs rated the support as not helpful. Of the CHVs who scored high adherence,

(51/54, 94%) CHVs were those who received helpful support and all the (3/54, 6%) CHVs who rated the support as not helpful. The difference in adherence between the two groups was not statistically significant (p= 1.00).

Field supervisors, also referred to as community health assistants (CHAs) to whom the CHVs reported to while carrying out field activities, were reported to have given support to (50/72, 69%) CHVs while (22/72, 31%) CHVs did not receive their support.
Amongst the CHVs who scored high adherence, (39/58, 67%) CHVs received support from CHAs whereas (19/58, 33%) CHVs did not receive support from the CHAs. The difference in adherence between the two groups was not statistically significant (p= 0.53).

Those CHVs who reported that they administered Praziquantel to the community members after a meal as per the drug intake requirements were (62/72, 86%) CHVs, while (10/72, 14%) CHVs reported otherwise. CHVs who reported that community members who had access to clean drinking water to enable them to take the treatment were (64/72, 89%), whereas (8/72, 11%) CHVs reported that community members did not have access to clean drinking water.

Exposure to health messages to the community was reported to be done once a year during the MDA exercise by (38/72, 53%) CHVs and throughout the year by (34/72, 47%) CHVs. Interestingly, there was an equal proportion of CHVs who scored high adherence in villages that received health messages once a year and throughout the year.

Awareness of intervention activities was done in the community through various means including handing out flyers by (34/72, 47%) CHVs, visiting participants door to door by (58/81%) CHVs and hanging posters in the community by (3/72, 4%) CHVs.

There were (9/72,13%) CHVs from those who indicated 'other' as to how they created awareness, 5/72, 7% CHVs said they created awareness in a '*baraza*', a Swahili term to indicate a public meeting in the community, 1/72,1% CHV used a public-address system while another 1/72, 1% CHV went through the assistant chief's office to talk about the exercise (See Appendix XII).

3.4.3 Quality of delivery

This section focused on the quality of delivery, that is, how the CHVs delivered the content of the intervention activities, further details are presented in Appendix X.

Majority of the CHVs indicated that they visited all the households in their allocated list (54/72, 75%) while the other CHVs reported to not having visited the households. Of the 18 CHVs who did not visit all their households, 11 said that no one was at home during the visit, 4 said they were limited because of time and only 1 mentioned that they had no access to the home (See Appendix XII).

For the community members who were absent during the intervention activities, 13 CHVs said they left the drugs with the family while 31 CHVs said they did not give the treatment and returned the tablets to the project. Twenty-seven of the CHVs who mentioned 'other' stated that they visited the homes the following day (See Appendix XII).

After administration of Praziquantel in each household, (60/72, 83%) CHVs said they waited for side effects of the drugs while (12/72, 17%) CHVs said they did not wait for side effects from the drugs. Among those who scored high adherence, (51/58, 88%) CHVs were those who waited for side effects while (7/58, 12%) CHVs did not wait for side effects.

There was evidence of an association (p=0.05), though not significant, between those who scored high adherence and those who waited for side effects after administration of Praziquantel. This variable was included in the regression model.

Among the CHVs who reported that they waited for side effects in the community members, (37/60, 62%) CHVs said they waited for up to ten minutes while the rest, (23/60, 38%) CHVs waited for more than ten minutes after administration. Among the CHVs who scored high adherence, (32/51, 63%) CHVs waited for up to ten minutes while (19/51, 37%) CHVs waited for more than ten minutes.

Some (62/72, 86%) CHVs reported that community members experienced mild side effects from the treatment, while (10/72, 14%) CHVs reported no side effects were experienced by the community members. The CHVs who reported mild side effects from treatment in the community members managed the patients using various methods; 22/62, 35% CHVs assured community members that the side effects would disappear, 9/62, 15% CHVs advised them to take water or porridge where available, 16/62, 26% CHVs referred the community member to the nearest health facility while 9/62, 15% CHVs advised them to take painkillers.

Community members who were reported to have experienced serious side effects from the treatment was by (32/72, 44%) CHVs, while (40/72, 56%) CHVs said they did not encounter serious side effects from the treatment. All the (32/32, 100%) cases were referred to the nearest health facility for management.

Majority (61/72, 85%) CHVs reported to their supervisor during the intervention activities as outlined in the guideline, among those who scored high adherence, (48/58, 83%) CHVs reported to their supervisors while (10/58, 17%) CHVs did not report to their supervisor.

Interestingly, the majority (42/61, 69%) CHVs who reported to their supervisor did so only once during the whole exercise. Among those who scored high adherence, (18/48, 37%) CHVs reported daily while (30/48, 63%) CHVs reported only once during the whole MDA exercise. There was evidence of an association, though not significant, between adherence and reporting frequency with a p-value of 0.05.

When administering Praziquantel to the community members, the CHVs gave an estimated duration of the time they spent on an individual as well as the household. A higher number (35/72, 56%) CHVs spent up to five minutes per individual compared to (27/72, 44%) CHVs who spent more than five minutes per individual. In total, 49 CHVs scored high adherence, where (27/49, 55%) CHVs spent up to 5 minutes per individual and (22/49, 45%) CHVs spent more than 5 minutes per individual.

Some CHVs admitted that they spent more time administering Praziquantel to children, (64 /72, 89%) CHVs while only a small percentage (8/72, 11%) CHVs said they did not spend more time administering Praziquantel to children.

In each household, (48/68, 71%) CHVs reported that they spent up to 30 minutes administering Praziquantel while (20/68, 29%) CHVs reported that they spent more than 30 minutes administering Praziquantel. Among the CHVs who scored high adherence, (40/57, 70%) CHVs spent up to 30 minutes compared to (17/47, 30%) CHVs who spent more than 30 minutes.

Only (11/72, 15%) CHVs reported to have administered Praziquantel to each household member in all their visits. The main reason for these low numbers was eligibility of household members to take the treatment as indicated in the guidelines, for example, pregnancy (55/72,

76%), sickness (33/72, 46%) and children below 5 years (52/72, 72%) were not given the treatment. Others community members who were not given the medication were absent (38/72, 53%) or refused (34/72, 47%) as shown in Appendix XII.

3.4.4 Participant responsiveness

This section focused on participant responsiveness to assess how the community members engaged with the CHVs during the intervention activities. The questions included community member's willingness to participate, their acceptance in taking Praziquantel and support from community members in convincing others of MDA benefits. The results are shown in detail in Table 3.5.

All CHVs reported that community members engaged with them to ask questions regarding the intervention, however not all community members accepted treatment as was reported by (49/72, 68%) CHVs, only (23/72, 32%) CHVs reported acceptance by community members to take treatment.

Among those who scored high adherence, (21/58, 36%) CHVs reported acceptance while (37/58, 64%) CHVs reported refusal by the community members to take treatment. There was no significant association between adherence and acceptance to take treatment however the p-value of 0.2 was included in the regression model.

Those who refused treatment were convinced that the drugs had harmful side effects (33/72, 46%), others said the drugs were too big (23/72, 32%), while others refused due to religious inclinations (22/72, 31%), lack of water (14/72, 19%) and bitterness of the drugs (10/72, 14%) (See Appendix XII).

CHVs who expressed that they found it difficult to convince participants of the benefits of Praziquantel treatment were (51/72, 71%) CHVs. Among those who scored high adherence, (42/58, 72%) CHVs were those who had difficulty convincing community members of benefits of treatment, while (16/58, 28%) CHVs faced no difficulty convincing the community members.

Some community members helped convince other community members about the intervention as was reported by (62/72, 86%) CHVs, among these, (51/58, 88%) CHVs scored high adherence. During the questionnaire interview, some of the CHVs mentioned village elders and gatekeepers as some of the key players in convincing the community to take treatment.

Table 3.5 Association of participant responsiveness and adherence score

Participant responsiveness

Variable	**N=72 n (%)**	**Adherence**		**P-value**
		High	**Low**	
Participants acceptance to take Praziquantel during MDA				
Yes	23 (32%)	21 (36%)	2 (14%)	0.20
No	49 (68%)	37 (64%)	12 (86%)	
Difficulty in convincing participants about the benefits of treatment				
Yes	51 (71%)	42 (72%)	9 (64%)	0.53
No	21 (29%)	16 (28%)	5 (36%)	
Support from other villagers to convince others to take treatment				
Yes	62 (86%)	51 (88%)	11 (79%)	0.40
No	10 (14%)	7 (12%)	3 (21%)	

3.4.5 Background characteristics of CHVs

This section focused on the socio-demographic and socio-economic factors of individual CHVs that possibly influenced their adherence to the guidelines (See Appendix XI).

Amongst the CHVs who scored high adherence, (44/58, 76%) were female CHVs while (14/58, 24%) CHVs were males, this difference was not statistically significant (p=0.74).
Of the 33 CHVs categorised in the 25-44 age group, (27/49, 55%) CHVs scored high adherence compared to (22/49, 45%) CHVs in >45-year age group who scored high adherence, overall there was no significant difference in the two groups.

Among the CHVs who scored high adherence, (49/58, 85%) CHVs were non-salaried workers while (9/58, 15%) CHVs were salaried workers. The difference in adherence in the two groups was not statistically significant (p=0.70).

Among the CHVs who scored high adherence, (31/58, 53%) CHVs were those with less experience, while (27/58, 47%) CHVs were those who had more experience. This difference in adherence in the two groups was not statistically significant (p=0.13), however, it was included as a potential determinant in the regression model.

Among those who scored high adherence, (32/58, 55%) CHVs received support, while (26/58, 45%) CHVs did not receive any support. The difference in adherence in the two groups was not statistically significant (p=0.24), however, this variable was included as a potential determinant in the regression model.

3.5 Logistic regression to determine the association of variables between measured adherence and determinants of adherence

This section describes the association between measured adherence and determinants of adherence. Eight variables that had a p-value of 0.25 or less were selected to be included in the model to measure association with adherence as previously described in section 2.8. Each variable was run independently in a logistic model and the results reported were crude odds ratios as shown in Table 3.6.

Table 3.6 The association of measured adherence and determinants of adherence

Variable	***Crude odds ratio (95% CI)***	***p-value***
Sex	1.26 (0.34-4.64)	0.73
Age group	1.23(0.37 – 4.34)	0.75
Number of MDA	3.19(0.81 – 12.65)	0.10
Other CHV support	2.22 (0.66-7.43)	0.20
Understand guidelines	5 (0.889-28.10)	0.10
Wait for side effects	4.05 (1.05-15.59)	0.04
Reporting frequency	7.20 (0.86-60.11)	0.07
Acceptance to take Praziquantel	3.41 (0.69-16.70)	0.13

There was no association between sex or age group with measured adherence. Waiting for side effects was found to have an association with the quality of delivery (p= 0.04). The remaining variables were not associated with adherence.

In conclusion, the odds of adherence were significantly higher for the CHVs who waited for side effects (4.05) in the community members compared to those who did not (95% CI:1.05-15.59). This indicates increased odds of adherence of CHVs who waited for side effects.

CHAPTER FOUR- DISCUSSION

4.1 Introduction

The objectives of this study were to measure adherence of CHVs to the MDA guidelines for Schistosomiasis and to identify the determinants of adherence to the mass drug administration programme in Western Kenya. In this section, the findings are discussed in light of existing evidence and in line with the study objectives.

Adherence

Content and coverage were both delivered with high adherence to the guidelines by the CHVs. Content was however shown to be an important component with regard to adherence as a higher number of CHVs recorded the highest possible score in this component of adherence.

Content in this study was described as all the key procedures the CHVs were to take to ensure that the intervention was delivered. The main procedures were correct usage of the dosing pole, direct-observed treatment, proper administration of treatment, creating awareness prior to treatment and recording those who took the treatment.

Coverage scores were observed to be lower compared to content; this was mainly because the CHVs did not visit all homes in their allocated list as well as the community members who were ineligible to take the treatment. Although the overall adherence was high, which is considered good in implementation research, the lower coverage rates also had an impact on the adherence measured.

In this study, duration and frequency were not included to measure adherence. Initially, the programme managers allocated one week for intervention activities (16), but due to the unique requirements of each household, adherence could not be determined using this component. Frequency of the intervention activities was determined by the project timelines, which was annually and twice over four years (15) thus it was not applicable to measure this component.

In a similar study by Toomey et al. content and duration of the intervention were measured and the results indicated that intervention content was delivered with high fidelity (82%) while intervention duration was shown to have deviated significantly in the first session (57). Similar implementation studies have recorded adherence from 60% and only a few studies have recorded levels higher than 80% (59).

The results from this study show that CHVs adhered to the MDA guidelines in the three counties, where 81% of them scored high adherence. The finding confirms that content, which is the key ingredient in any intervention, is vital to achieving the goals of the programme as prescribed by the designers, thus achieving high adherence. Based on these results and considering the contextual limitations, the adherence measured can be considered sufficient.

The study also examined several determinants associated with adherence. Quality of delivery was shown to have an association with adherence. This study revealed that waiting after administering treatment is associated with high adherence to the guidelines. According to the MDA guidelines, all CHVs are required to directly observe treatment to ensure that community members swallow all the tablets and to manage the side effects of the treatment (17).

In previous MDA activities, CHVs directly observed the community members while taking treatment to ensure drug compliance (8), conversely Odhiambo et al. noted with concern that direct observation was a challenge since many of the community members preferred to take the treatment at their preferred time while still others could not afford a meal (16).

The high adherence associated with waiting for side effects can be attributed to the CHVs time allocated for each household. Ideally, if each CHV is able to administer and observe treatment for all the households, then implementation adherence can be presumed to be high.

The main challenge with this, however, is the limited window of time that the CHVs work with, the intervention activities are carried out mainly during the day when community members may not be available. CHVs may often not wait since they have other households to treat. In a similar study, nurses were unable to deliver health information due to the restricted time allocated and this in turn negatively affected the adherence (59).

This study has demonstrated that direct observed treatment is important for case-management, compliance to treatment and recording treatment coverage. CHVs in this study reported that they did not give all the community members treatment, but they were still able to meet the programme's goals of treatment coverage.

The study revealed that high adherence was attributed to the simplicity of guideline. The CHVs reported that the guideline for MDA was easy to understand and detailed enough to allow them to carry out their duties. Although some CHVs felt that sections of the guideline were hard to understand or vague, CHVs scored high adherence.

This confirms literature by Carroll et al. who argue that simple but specific interventions have a higher likelihood of being implemented with high adherence than those that are too complex or vague in their description (18).

One feature of the guideline that contributed to the ease of understanding was the language used during the training; the training was conducted in the local language, that is, Kiswahili and Dholuo and some of the technical terms like Schistosomiasis were substituted for bilharzia which is the common term used in the community. The sections which were hard, for example, the life cycle and side effects of the drugs, possibly hindered the CHVs from engaging with and giving correct information to the community members in the villages.

A study by Branden et al. describes how a detailed, easy to use manual aided nurses during health visits to patients. The nurses implemented the intervention with high adherence. Interestingly, only 40% of the nurses used the manual during the sessions with the patients (59).

Apart from the guidelines being easy to follow, the CHVs also indicated that they adhered to the guidelines as they believed the intervention was helping the community and were motivated to see the community Schistosomiasis free.

Another important determinant described here is strategies to facilitate implementation. Results from the study show that supervisory support was received by the CHVs from both the programme managers as well as the field supervisors. CHVs who rated supervisory support reported it as very helpful in allowing them to carry out their duties and score high adherence compared to those who did not receive any supervisory support.

According to the framework for implementation fidelity, there are two types of support given by programme managers, that is, monitoring and feedback by supervisors and training (18). Various studies highlight the importance of supervisory support to positively impact adherence to guidelines and therefore improving clinical outcomes.

A study by Lawton et.al. 2015 reviewed responses from health care professionals which showed support from supervisors was critical for successful implementation (49). Another study by Chung et.al. to understand role performance of CHVs in Sarawak, Malaysia, showed that supervision was an important factor to good performance by the CHVs, they further argue that poor supervision contributes to the CHVs low morale and poor productivity (41).

Although the study did not show a strong association between adherence and supervisory support it is worthy to note that the CHVs rated the support they received as helpful. It can be suggested from these studies that monitoring and feedback is vital to improving performance of the individual delivering an intervention. It is also particularly important to ensure that any deviations from the programme can be identified and corrected as soon as they are reported (18).

All CHVs received a one-day training before the intervention activities which was necessary for the CHVs to understand the intervention and their role in the programme. Chung and colleagues highlight that training is an important factor affecting CHV duties and that the training materials should be developed specifically for CHVs, they further suggest that refresher trainings are important to maintain the skills and knowledge which would be otherwise lost (41).

Elsewhere, refresher training has been shown to further impact knowledge and understanding of the CHVs. Training should be tailor-made so that those who have less experience conducting MDA may receive more detailed instruction and supervision (40). The training received by the CHVs was important not only to those who were conducting the exercise for the first time but also to those with previous experience.

Participants responsiveness to the intervention materials was shown to be nominal. The CHVs reported that not all community members accepted treatment due to various reasons. Carroll et al. argue that participants non-engagement with an intervention can be a major reason for its failure thus an intervention's uptake is dependent on its acceptability by those receiving it (18).

In a qualitative study by Omedo et al., 2012, the community members applied a 'wait and see attitude' to observe the experience of other community members before they decided to take the medication. Others refused to take the drugs because of fear of side effects that they witnessed from their neighbours who had participated in the MDA (8).

Other reasons for non-compliance by the community include, unpleasant side effects of the drugs, some patients may feel less inclined to complete the full dosage during recovery (18), religious affiliation, suspicion about the drugs (8), and the bad taste of drugs (63).

All the above reasons were cited by the community members in the current study, the majority of the CHVs reported that they experienced difficulty in convincing community members about the MDA exercise. It is possible that CHVs insufficient knowledge of side effects and life cycle of Schistosomiasis may have contributed to this.

It is also possible that during the awareness campaigns, the CHVs may not have given enough information to the community. It has previously been shown that community awareness campaigns increase acceptability of programmes and participation by the community members (16). Titaley et al. report that community members were non-receptive toward drug distributors because they lacked adequate information and the community had no confidence in them (40).

Finally, this study revealed that CHVs socio-demographic and socio-economic characteristics are not associated with adherence. This finding contrasts that of Chung et al. where age, education and marital status influenced the performance of the CHVs (41), elsewhere, CHVs sex and age were shown to be significantly associated with having a good knowledge of onchocerciasis (43). Branden et al. showed that high fidelity of an intervention was influenced by experience, motivation and educational background of nurses (59).

The findings would indicate that socio-demographic and socio-economic characteristics of the CHVs in this study is not an important factor to consider when selecting CHVs, however, further research is required to confirm this.

4.2 Limitations of the study

In considering the findings of this study, it is important to bear in mind the following limitations.

1. The study relied on self-reported data by the CHVs which affects the validity and accuracy of the reported data, the additional use of observational data would have proven useful in this study.
2. The study was conducted after the MDA activities were completed; this may have contributed to recall bias in the CHVs responses.

3. There have been no previous studies on implementation research carried out in this region and thus there was limited information to reference from.
4. The study was cross-sectional, and the findings did not establish a causal relationship to the variables.

4.3 Conclusions

The findings of this study provide a basis for measuring the performance of CHVs using a proven framework to understand how the different components affect adherence to MDA guidelines. The use of the conceptual framework by Carroll et al. (18) provides a guide for measuring an intervention process which allows researchers to better interpret study findings.

Adherence to the training guidelines by the CHVs was high and thus intervention activities were implemented with high adherence, in particular, the content of the intervention was delivered with high adherence.

There was a strong relationship between adherence and quality of delivery, in other words, the high adherence measured can be attributed to the quality of delivery by the CHVs. Furthermore, the high adherence measured was also complemented by ease of understanding of the guideline, support strategies and good participant responsiveness.

It is important that programme managers monitor the process of implementation to ensure that programmes are implemented as intended. This is important for planning future interventions that CHVs are involved in.

The results of this research demonstrate the contribution of implementation research to health programmes. This implies the need for future research on determining the effectiveness of interventions and their key players.

4.4 Recommendations

Based on the findings from this study, the following are the recommendations:

1. Directly observed treatment and waiting for side effects in community members should be encouraged by the programme managers for MDA to ensure that all community members are taking the medication and thus achieve the 75% target.
2. Support structures need to be strengthened to encourage the CHVs to report frequently to their supervisors and vice versa to ensure that any unforeseen challenges can be dealt with as they occur.
3. To allay fears of treatment, education and awareness campaigns would need to be conducted regularly by programme managers to ensure acceptability of treatment by the community. CHVs would also need to be empowered with more information as well, thus a simple descriptive manual should be provided for reference during MDA activities.
4. Policymakers, programme managers and other relevant stakeholders need to strengthen the roles of the CHV by defining strategies that allow them to fully function in an enabling environment thereby pushing forward the NTD agenda. This can only be possible where there is ongoing evaluation of intervention activities.
5. There is a need for a qualitative study to be conducted to futher explore some of the responses by the CHVs, for example, their motivation to follow the guidelines and supervisory support.

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APPENDICES

Appendix I: Plagiarism declaration

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | FACULTY OF HEALTH SCIENCES

I _CHARITY WARIGIA HUNGU (Student number: 1688052) am a student registered for the degree of _Master of Science in Epidemiology (in Implementation Science) _ in the academic year _2019.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: _____  _____ Date: __4th October 2019_____

Appendix II: Information sheet

Study title: Adherence of community health volunteers to mass drug administration guidelines for schistosomiasis control in western Kenya.

Greeting: Hello

Introduction:

My name is Charity Hungu and I am a student from the School of Public Health, University of Witwatersrand, South Africa. The school within the university carries out research on human health to improve it and reduce the burden of disease in human populations. I want to do a study on adherence of community health volunteers to mass drug administration guidelines for schistosomiasis control in western Kenya. In this study, I would like to understand how you use the guidelines for giving praziquantel for schistosomiasis control in your community. I would then like to invite you to be part of this research study.

What is involved in the study? I will ask you questions on how you use the guidelines for the mass drug administration and how they guide you while administering praziquantel in the community. I will interview other community health workers as well. The questions in the questionnaire will ask some questions about you, the kind of support that you are given during the mass drug administration, how well the community members respond to the programme, the content of the guidelines, coverage of the activities and how the guidelines help you to administer the treatment. The time required to answer all the questions in this questionnaire is one hour.

Risks of being in the study? There are no risks associated with participating in this study.

Benefits of being in the study? You will not benefit directly, but your participation will be valuable as you will contribute towards the fight against schistosomiasis in western Kenya by

helping us understand how to make the mass drug administration exercise reach more members of the community.

Participation is voluntary: If you agree to participate in the study, you have the right to withdraw your participation at any time in the study if you feel the need to, you will not be penalized for withdrawing participation or coerced to return to the study.

Reimbursements for "out of pocket" expenses? There will reimbursements for transport in this study.

Confidentiality. If you agree to participate in the study, we will ensure that your name will not be recorded with the information you have given. Your personal information will never be made public to other researchers or anyone else. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee and the Medicines Control Council.

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Appendix III: Informed consent form

I agree to participate in the study on adherence of community health volunteers to mass drug administration guidelines for schistosomiasis control in western Kenya. I understand all the information outlined in the information sheet. I confirm that I have the right to withdraw my participation at any time in the study if I feel the need to and that I will not be penalized for withdrawing participation or be coerced to return to the study.

Name ..... Signature .....

Date .....

Appendix IV: Questionnaire for Community Health Volunteers (REDCap)

Background characteristics of CHVs

Interviewer ID	_____
Record ID	_____
1. Sex of participant	◯ Female ◯ Male
2. Age of participant	_____
3. Highest level of education completed	◯ No formal education ◯ Primary school ◯ Secondary school ◯ Higher (specify)
4. Marital status of participant	◯ Never married ◯ Married ◯ Separated ◯ Widowed
5. Occupation of participant	◯ Not working ◯ Working part-time ◯ Business owner ◯ Salaried worker ◯ Volunteer work ◯ Other
6. How many mass drug administration exercises for bilharzia have you conducted?	_____
7. Personally, do you think everyone eligible to take praziquantel should do so during the MDA exercises?	◯ Yes ◯ No ◯ Unsure
Please give a reason for your answer above	_____
8. Do you believe that mass drug administration is effective for controlling bilharzia?	◯ Yes ◯ No ◯ Unsure
Please give a short reason for your previous answer	_____
9. How familiar are you with the guidelines for mass drug administration for bilharzia control?	◯ Very familiar ◯ Somewhat familiar ◯ Not familiar at all ◯ Not sure
10. Do you think there are any particular skills required to follow the guidelines for mass drug administration for bilharzia control?	◯ Yes ◯ No ◯ Not sure
If you answered yes to the previous question, do you think you have the skills required to follow the guidelines for mass drug administration for bilharzia control?	◯ Yes ◯ No ◯ Not sure
11. Are you confident that you can follow the guidelines for mass drug administration for bilharzia control?	◯ Yes ◯ No ◯ Not sure

12. Do you have motivation to follow the guidelines for mass drug administration for bilharzia control?
- ◯ Yes
- ◯ No
- ◯ Not sure

13. Do other community health volunteers support you to follow the guidelines for mass drug administration for bilharzia control?
- ◯ Yes
- ◯ No
- ◯ Not sure

Please give a short reason for your previous answer _____

Complexity of intervention

14. Overall, what do you think about the training you used for bilharzia mass drug administration, Is it?
- ◯ Easy to understand
- ◯ Hard to understand
- ◯ Don't know

15. If any part of the training for bilharzia was hard to understand, please give the section and a brief description _____

16. What do you think about the guidelines for mass drug administration for bilharzia? Is it
- ◯ Detailed (give enough information)
- ◯ Vague (did not give enough information)
- ◯ Don't know

17. If there is a section of the guideline for mass drug administration that does not give enough Information, please give the section and a brief description _____

18. Were you able to understand all the information in the training?
- ◯ Yes
- ◯ No

Strategies to facilitate implementation

19. Were you given any supervisory support by the program managers during the mass drug administration exercise?
- ◯ Yes
- ◯ No

20. How was the support?
- ◯ Not helpful
- ◯ Very helpful
- ◯ Don't know

21. During the mass drug administration for bilharzia, were you provided with the following? Tick what is applicable
- ☐ Praziquantel Tablets/ drugs
- ☐ Treatment booklets
- ☐ Dosing pole
- ☐ T-shirts
- ☐ Bag
- ☐ Pen

22. Did you create awareness before the mass drug administration for bilharzia exercise?
- ◯ Yes
- ◯ No

23. If you created awareness in the villages before the MDA exercise, did you?
- ☐ Encourage community members to take deworming tablets
- ☐ Educate community members on the importance of taking the drugs
- ☐ Other

24. How was awareness for the mass drug administration done?
- ☐ Give materials with information about bilharzia to the community members
- ☐ Visit the participant's door to door
- ☐ Hang posters in the villages
- ☐ Other

25. Did you receive any training before the mass drug administration exercise?
- ◯ Yes
- ◯ No

26. Please state how many MDA trainings you participated in before you delivered the drugs to the community members

_____

27. On the day of the MDA exercise, did you carry enough deworming tablets for the households you were to give?
- ◯ Yes
- ◯ No
- ◯ Don't know

28. If you answered no in the previous question, please give a reason why you did not carry enough tablets to the households you were to visit?
- ◯ Not enough tablets were issued by the managers of give the program
- ◯ The numbers of household members were more than expected on that day
- ◯ Drug stock out
- ◯ Other

29. What did you do with the remaining drugs from the mass drug exercise?
- ◯ Kept the drugs
- ◯ Returned the drugs to the project
- ◯ Threw the drugs away
- ◯ Other

30. What did you do with the treatment booklets at the end of the drug administration exercise?
- ◯ I kept the treatment booklets
- ◯ Returned the treatment booklets
- ◯ Don't remember
- ◯ Other

31. Did you receive supervisory support from your field supervisor when conducting the mass-drug administration exercise?
- ◯ Yes
- ◯ No
- ◯ Don't know

Quality of delivery

32. Did you visit all the homes to give deworming tablets in your allocated list of households?
- ◯ Yes
- ◯ No
- ◯ Don't know

33. If you answered no to the previous question, what reason would you give why you did not visit all the homes in your allocated list?
- ☐ There was no time to visit all the homes
- ☐ The homes were far
- ☐ The homes were inaccessible
- ☐ There was no one at home
- ☐ Other

34. Did you observe all members to confirm that they took the drugs when you visited the households?
- ☐ Yes
- ☐ No
- ☐ Not sure

35. Did you give all the household members tablets?
- ◯ Yes
- ◯ No
- ◯ Don't know

36. If you answered no in the previous question, Please state why you did not give all household members tablets?
- ☐ Some members were absent
- ☐ Pregnant member
- ☐ Child under 5 years
- ☐ Sick member(s)
- ☐ Members refused
- ☐ Other

37. If you did not find all the household members at the home, what didyou do?
- ☐ Leave the drugs with the family
- ☐ Did not give the drugs and returned them to project
- ☐ Other

38. For the members who were absent during deworming days, did you revisit the home?
- ◯ Yes
- ◯ No

39. Did you record all the people that you dewormed in the treatment booklet provided?
- ◯ Yes
- ◯ No

40. After administering praziquantel in the households, did you wait to make sure that no one experienced side effects?
- ◯ Yes
- ◯ No
- ◯ Don't know

41. Please state how long you waited for any side effects after administering praziquantel in the households?
- ◯ 0-5 minutes
- ◯ 6-10 minutes
- ◯ More than ten minutes

42. After administering praziquantel in the households, did any participant experience mild side effects from the drugs?
- ◯ Yes
- ◯ No
- ◯ Don't know

43. How did you manage those participants who experienced mild side effects from the drugs you administered?

_____

44. After administering praziquantel in the households, did any participant experience serious side effects from the drugs?
- ◯ Yes
- ◯ No
- ◯ Don't know

45. How did you manage those participants who experienced serious side effects from the drugs you administered?

_____

46. Did you report to your field supervisor while conducting the mass drug administration exercise?
- ◯ Yes
- ◯ No

47. How often did you report to your field supervisor during the MDA exercise?
- ◯ More than once a day
- ◯ Once a day
- ◯ Once a week
- ◯ Once during the whole exercise
- ◯ Don't know
- ◯ Other

Participant responsiveness

48. In your opinion, do the participants engage with you to ask questions about the mass drug administration and bilharzia in general?
- ◯ Yes
- ◯ No

49. Do all the participants accept to take Praziquantel during the MDA exercise?
- ◯ Yes
- ◯ No

50. If your previous answer was no, what are some of the reasons that some participants refuse to take praziquantel during the MDA exercise?
- ☐ Drugs are bitter
- ☐ Drugs are too big
- ☐ No water is provided
- ☐ Drugs have harmful side effects
- ☐ Religious beliefs don't allow
- ☐ Other

51. Do you find it difficult to convince the participants about the benefits of taking praziquantel during awareness campaigns and during the mass drug administration exercise?
- ◯ Yes
- ◯ No

52. If you have indicated other, please give a short description for your answer

_____

53. Are there members of the village who are not community health volunteers who have helped you convince participants to take take praziquantel?
- ◯ Yes
- ◯ No

Coverage

54. Do you know the number of households that you are supposed to administer treatment to within the community?
- ◯ Yes
- ◯ No

55. Did you visit all the homes in your assigned village to create awareness before the mass drug administration
- ◯ Yes
- ◯ No
- ◯ Don't know

56. Did you visit all the homes to give deworming tablets in you allocated list of households?
- ◯ Yes
- ◯ No
- ◯ Don't know

57. Did you achieve the programme target for the number of households to give the praziquantel to?
- ◯ Yes
- ◯ No

58. What distance in kilometers on average did you cover during the mass drug administration?
- ◯ less than 5km
- ◯ 5-10 km
- ◯ more than 10 km

Content

59. Did you correctly administer the praziquantel tablets to each household member?
- ◯ Yes
- ◯ No

60. When you were giving instructions of the procedure to take the praziquantel drugs, did you ensure that every household member washed their hands before taking the treatment?
- ◯ Yes
- ◯ No

61. Were all the household members able to take the praziquantel tablets after a meal?
- ◯ Yes
- ◯ No

62. Did all the household members have access to drinking water to allow them to take the praziquantel tablets?
- ◯ Yes
- ◯ No

63. What did you use to know the number of praziquantel tablets to the give community members?

64. Were you able to interpret correctly the markings on the dosing pole while administering the drugs for bilharzia?
- ◯ Yes
- ◯ No

Duration

65. How many days did you take to administer the drugs for bilharzia in your village?
- ◯ Less than one day
- ◯ 1-3 days
- ◯ 4-6 days
- ◯ More than six days

66. Do you administer the praziquantel tablets to the household members together or individually (one person at a time)?
- ◯ Individually
- ◯ To all the household members at the same time

67. If you answered individually in the previous question, how long do you spend administering praziquantel to one person?
- ◯ 0-5 minutes
- ◯ 6-10 minutes
- ◯ more than 10 minutes

68. When giving praziquantel to children, do you spend more time than the average time you would spend if administering praziquantel tablets to an older person?
- ◯ Yes
- ◯ No

69. On average, how much time do you spend in each household while administering the drugs for bilharzia?
- ◯ Less than 15 minutes
- ◯ 15 - 30 minutes
- ◯ 31 - 60 minutes
- ◯ more than an hour
- ◯ Don't know

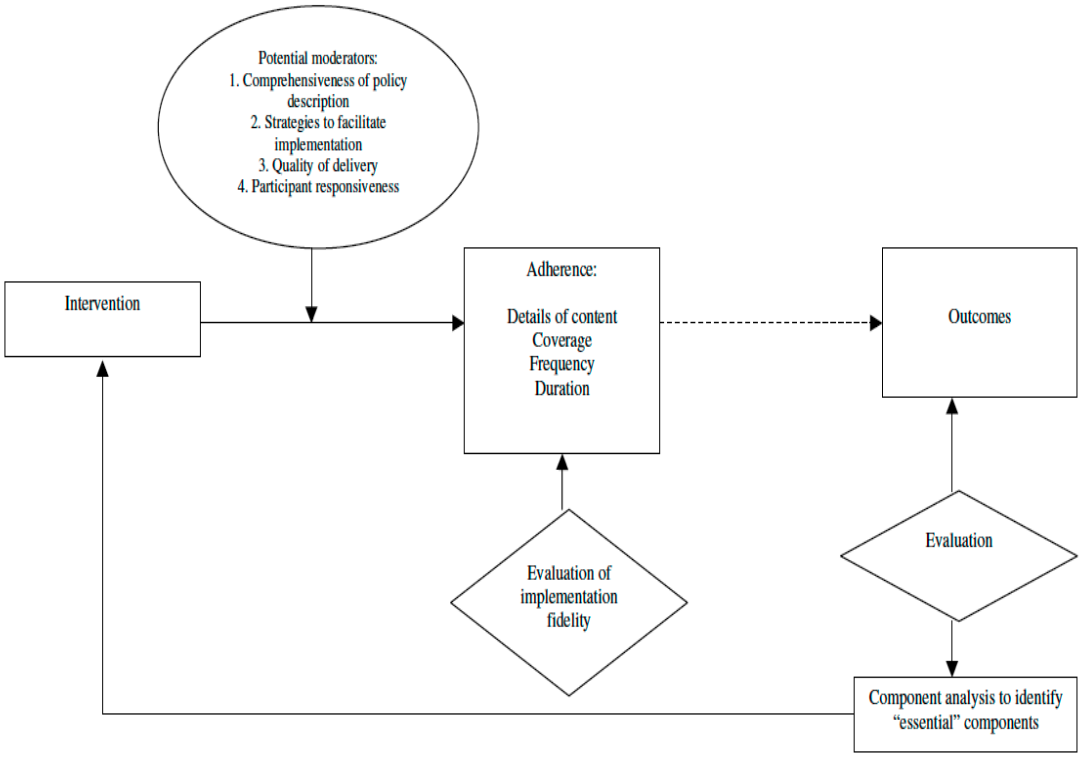
Frequency

70. How many times in a year are mass drug administration exercises conducted within your village?
- ◯ Once a year
- ◯ Twice a year
- ◯ Don't know

71. When was the last time a mass drug administration was carried out in your village?
- ◯ This year
- ◯ Last year
- ◯ More than two years ago
- ◯ Never

72. How often does the community get exposure to bilharzia health education messages?
- ◯ Only during the MDA exercises
- ◯ Throughout the year even when no MDA exercise is being done
- ◯ Not sure

Appendix V: Conceptual framework for implementation fidelity



Appendix VI: Ethical clearance certificate from Human Resource Ethics Committee (HREC) University of the Witwatersrand

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Miss Charity Hungu

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M180147

NAME: (Principal Investigator)	Miss Charity Hungu
DEPARTMENT:	Epidemiology and Biostatistics Villages in Siaya, Kisumu and Homa Bay counties in Western Kenya
PROJECT TITLE:	Adherence of Community Health Volunteers to Mass Drug Administration Guideline for Schistosomiasis Control in Western Kenya
DATE CONSIDERED:	26/01/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Jabulani Ncayiyana
APPROVED BY:	Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	10/04/2018

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

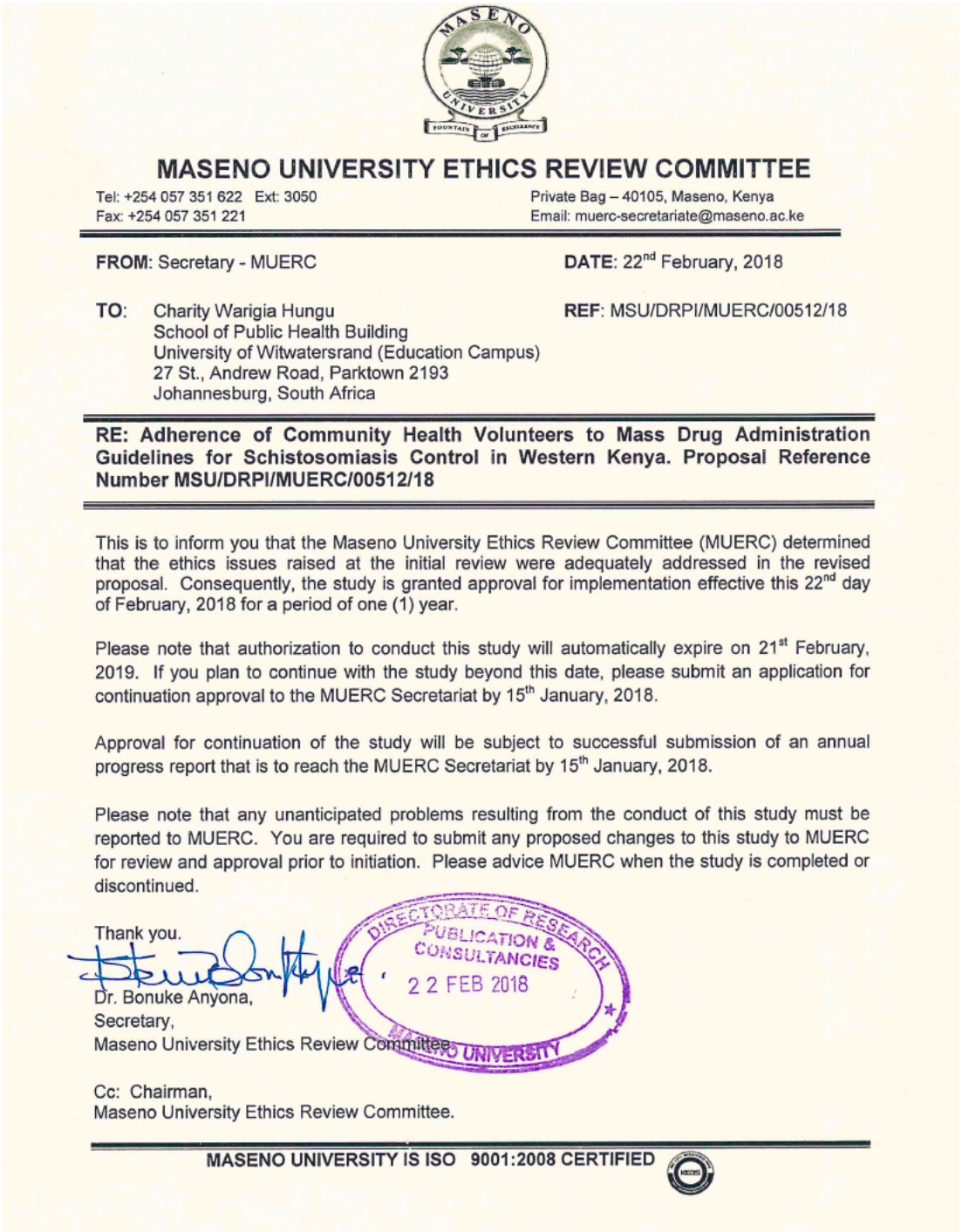
To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **January** and will therefore be due in the month of **January** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 15/04/2018

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix VII: Maseno University Ethics Review Committee clearance certificate



MASENO UNIVERSITY ETHICS REVIEW COMMITTEE

Tel: +254 057 351 622 Ext: 3050
Fax: +254 057 351 221

Private Bag – 40105, Maseno, Kenya
Email: muerc-secretariate@maseno.ac.ke

FROM: Secretary - MUERC

DATE: 22nd February, 2018

TO: Charity Warigia Hungu
School of Public Health Building
University of Witwatersrand (Education Campus)
27 St., Andrew Road, Parktown 2193
Johannesburg, South Africa

REF: MSU/DRPI/MUERC/00512/18

RE: Adherence of Community Health Volunteers to Mass Drug Administration Guidelines for Schistosomiasis Control in Western Kenya. Proposal Reference Number MSU/DRPI/MUERC/00512/18

This is to inform you that the Maseno University Ethics Review Committee (MUERC) determined that the ethics issues raised at the initial review were adequately addressed in the revised proposal. Consequently, the study is granted approval for implementation effective this 22nd day of February, 2018 for a period of one (1) year.

Please note that authorization to conduct this study will automatically expire on 21st February, 2019. If you plan to continue with the study beyond this date, please submit an application for continuation approval to the MUERC Secretariat by 15th January, 2018.

Approval for continuation of the study will be subject to successful submission of an annual progress report that is to reach the MUERC Secretariat by 15th January, 2018.

Please note that any unanticipated problems resulting from the conduct of this study must be reported to MUERC. You are required to submit any proposed changes to this study to MUERC for review and approval prior to initiation. Please advice MUERC when the study is completed or discontinued.

Thank you.

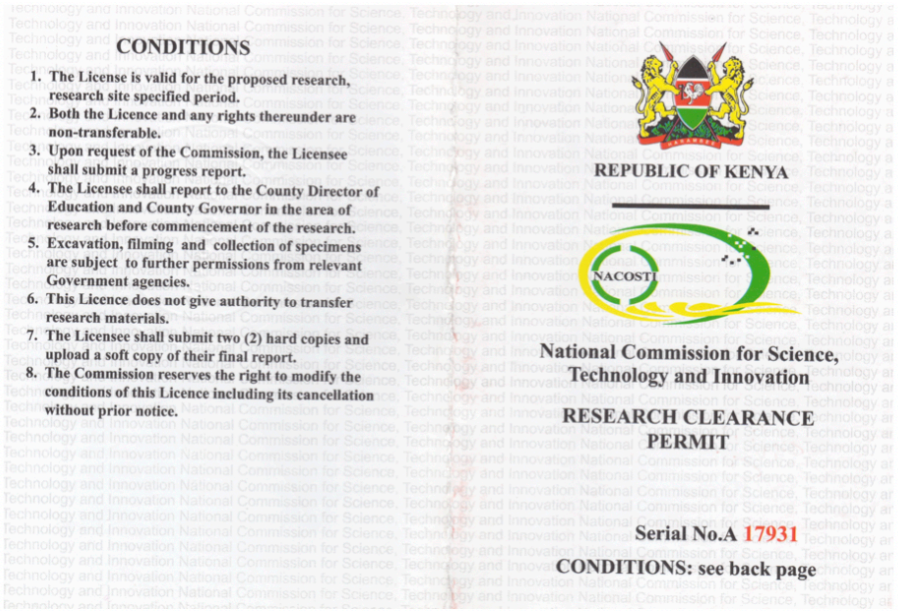
DIRECTORATE OF RESEARCH PUBLICATION & CONSULTANCIES 22 FEB 2018 MASENO UNIVERSITY

Dr. Bonuke Anyona,
Secretary,
Maseno University Ethics Review Committee

Cc: Chairman,
Maseno University Ethics Review Committee.

MASENO UNIVERSITY IS ISO 9001:2008 CERTIFIED

Appendix VIII: National Commission for Science Technology and Innovation (NACOSTI) permit



CONDITIONS

1. The License is valid for the proposed research, research site specified period.
2. Both the Licence and any rights thereunder are non-transferable.
3. Upon request of the Commission, the Licensee shall submit a progress report.
4. The Licensee shall report to the County Director of Education and County Governor in the area of research before commencement of the research.
5. Excavation, filming and collection of specimens are subject to further permissions from relevant Government agencies.
6. This Licence does not give authority to transfer research materials.
7. The Licensee shall submit two (2) hard copies and upload a soft copy of their final report.
8. The Commission reserves the right to modify the conditions of this Licence including its cancellation without prior notice.

REPUBLIC OF KENYA

National Commission for Science, Technology and Innovation

RESEARCH CLEARANCE PERMIT

Serial No.A 17931

CONDITIONS: see back page

THIS IS TO CERTIFY THAT:
MS. CHARITY WARIGIA HUNGU
of UNIVERSITY OF THE WITWATERSRAND , 0-202 Nairobi,has been permitted to conduct research in *Homabay , Kisumu , Siaya Counties*

on the topic: *ADHERENCE OF COMMUNITY HEALTH VOLUNTEERS TO MASS DRUG ADMINISTRATION GUIDELINES FOR SCHISTOSOMIASIS CONTROL IN WESTERN KENYA*

for the period ending:
15th March,2019

.....
Applicant's Signature

Permit No : NACOSTI/P/18/17060/21685
Date Of Issue : 16th March,2018
Fee Recieved :Ksh 1000

.....
Director General
National Commission for Science, Technology & Innovation

Appendix IX: Strategies to facilitate implementation table

Strategies to facilitate implementation

Variable	**N=72**	**Adherence**		**P-value**
	n (%)	**High**	**Low**	
Supervisory support from program managers				
Yes	67 (93%)	54 (93%)	13 (93%)	1.00
No	5 (7%)	4 (7%)	1 (7%)	
Rating of supervisory support				
Very helpful	64 (96%)	51 (94%)	13 (100%)	1.00
Not helpful	3 (4%)	3 (6%)	0	
Supervisory support from field supervisor				
Yes	50 (69%)	39 (67%)	11 (79%)	0.53
No	22 (31%)	19 (33%)	3 (21%)	
Administration of Praziquantel after a meal				
Yes	62 (86%)	49 (85%)	13 (93%)	0.68
No	10 (14%)	9 (15%)	1 (7%)	
Access to clean drinking water to take with Praziquantel				
Yes	64 (89%)	51 (88%)	13 (93%)	1.00
No	8 (11%)	7 (12%)	1 (7%)	
Exposure to schistosomiasis health messages				
Only during MDA exercises	38 (53%)	29 (50%)	9 (64%)	0.39
Throughout the year	34 (47%)	29 (50%)	4 (36%)	

Appendix X: Quality of delivery

Quality of delivery

Variable	**N=72 n (%)**	**Adherence**		**P-value**
		High	**Low**	
Wait after administering treatment				
Yes	60 (83%)	51 (88%)	9 (64%)	0.05
No	12 (17%)	7 (12%)	5 (36%)	
Duration CHV waited after giving Praziquantel				
0 - 10 minutes	37 (62%)	32 (63%)	5 (56%)	0.72
More than 10 minutes	23 (38%)	19 (37%)	4 (44%)	
Experience mild side effects				
Yes	62 (86%)	49 (85%)	13 (93%)	0.70
No	10 (14%)	9 (15%)	1 (7%)	
Experience serious side effects				
Yes	32 (44%)	24 (41%)	8 (57%)	0.37
No	40 (56%)	34 (59%)	6 (43%)	
Report to supervisor				
Yes	61 (85%)	48 (83%)	13 (93%)	0.68
No	11 (15%)	10 (17%)	1 (7%)	
Reporting frequency to supervisor				
Daily	19 (31%)	18 (37%)	1 (8%)	0.05
Once during the whole MDA	42 (69%)	30 (63%)	12 (92%)	
Average duration spent on administration of Praziquantel (individual)				
0-5 minutes	35 (56%)	27 (55%)	8 (61%)	0.76
More than 5 minutes	27 (44%)	22 (45%)	5 (39%)	
Average duration spent on administration of Praziquantel (household)				
0-30 minutes	48 (71%)	40 (70%)	8 (73%)	1.00
>30 minutes	20 (29%)	17 (30%)	3 (27%)	
More time spent administering Praziquantel to children?				
Yes	64 (89%)	51 (88%)	13 (93%)	1.00
No	8 (11%)	7 (12%)	1 (7%)	

Appendix XI: Results table of background characteristics of CHVs and adherence score

Background characteristics of community health volunteers

Variable	**n (%)**	**Adherence**		**P-value (exact test)**
		High	**Low**	
Sex				
Females	54 (75%)	44 (76%)	10 (71%)	0.74
Males	18 (25%)	14 (24%)	4 (29%)	
Age (years)				
25-44 years	33 (54%)	27 (55%)	6 (50%)	0.76
>45	28 (46%)	22 (45%)	6 (50%)	
Education				
Primary school	21 (29%)	17 (29%)	4 (29%)	1.00
Secondary school	51 (71%)	41 (71%)	10 (71%)	
Marital status				
Not Married	16 (22%)	13 (22%)	3 (21%)	1.00
Married	56 (78%)	45 (78%)	11 (79%)	
Occupation				
Non-salaried worker	62 (86%)	49 (85%)	13 (93%)	0.70
Salaried worker	10 (14%)	9 (15%)	1 (7%)	
Number of MDA exercises conducted				
1-2	42 (58%)	31 (53%)	11 (79%)	0.13
>2	30 (42%)	27 (47%)	3 (21%)	
Eligibility of community to take Praziquantel				
Yes	57 (79%)	47 (81%)	10 (71%)	0.47
No	15 (21%)	11 (19%)	4 (29%)	
Motivation to follow guidelines				
Yes	68 (94%)	55 (95%)	13 (93%)	1.00
No	4 (6%)	3 (5%)	1 (7%)	
Support from other CHVs to follow guidelines				
Yes	37 (51%)	32 (55%)	5 (36%)	0.24
No	35 (49%)	26 (45%)	9 (64%)	

Appendix XII: Multiple responses to determinants

Mulitple response table			
Variable	**Frequency (n)**	**Variable**	**Frequency (n)**
If members were absent, how did CHV administer treatment		***Reasons that CHV did not visit all homes***	
Left drugs with family	13	*No one at home*	11
Returned the drugs to project	31	*No time*	4
Other (Follow-up visit)	27	*Inaccessibility*	1
		Other	2
Reasons participants refuse to take Praziquantel		***Provisions for intervention activities***	
Drugs have harmful side effects	33	*Praziquantel*	72
Drugs are too big		*Treatment booklets*	70
Religious beliefs	23	*Dose pole*	70
No water is provided/available	22	*T-shirt*	59
Drugs are bitter	14	*Bag*	57
Other reasons	10	*Pen*	50
	12		
Reason that not all were given Praziquantel		***Support from other CHVs***	
Some were absent	38	*Mobilisation*	23
Pregnancy	55	*Interest in MDA*	6
Child below 5 years	52	*Distance unmanageable alone/ enjoyed working together*	3
Sick	33		
Refused	34		
Other	4		
Awareness during MDA		***No support from other CHVs***	
Hand out flyers	34	*Not trained*	10
Visit participants door-door	58	*No help was needed/ Wanted payment*	6
Hang posters in the community	3	*No response*	19
Other	9		

Appendix XIII: Guideline developed by the Ministry of Health for mass drug administration for schistosomiasis and soil-transmitted helminths in Kenya

ROLES IN COMMUNITY-BASED DEWORMING

One of the most important people in community-based deworming is you – the community health volunteer (CHV).

Why were you selected to become a CHV for community deworming?

The Ministry of Health has chosen community health volunteers like you to support it in ensuring people in your community are healthy and that worms are eliminated in Kenya. You are very important because you will help Kenya find the best way to remove worms as a public health problem in the country.

What are your specific roles as a CHV for deworming in the TUMIKIA project?

1. Educate community members about community-based deworming and benefits of deworming every six months
2. Give materials with information about worms to community members
3. Encourage community members to take the deworming tablets during planned deworming days
4. Pack and distribute sufficient deworming tablets for the planned household treatments
5. Visit homes to give deworming tablets to household members
6. Plan for revisits (follow-up) to deworm household members who are not at home on planned deworming days
7. Record the number of people that you have dewormed in the treatment booklets provided
8. Promptly return treatment booklets and remaining deworming tablets to your Community Health Assistant (CHA)
9. Manage mild side effects should they occur at the household and refer any cases of serious side effects to the nearest health facility
10. Report to your Community Health Assistant (CHA) as regularly as guided