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Impact of two rounds of praziquantel mass drug administration on *Schistosoma mansoni* infection prevalence and intensity: a comparison between community wide treatment and school based treatment in western Kenya

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ABSTRACT

This study compared the effectiveness of the community-wide treatment and school-based treatment approaches in the control of *Schistosoma mansoni* infections in villages with ⩾25% prevalence in western Kenya. Stool samples from first year students, 9–12 year olds and adults (20–55 years) were analyzed by the Kato–Katz technique for *S. mansoni* eggs. After two rounds of treatment, *S. mansoni* prevalence and intensity levels significantly declined in both treatment approaches. Prevalence comparisons between the two approaches did not show any significant differences following treatment. However, infection intensity levels in the 9–12 year old school-attending pupils were significantly higher in the community-wide treatment arm than in the school-based treatment arm. Nevertheless, significant reductions in *S. mansoni* infection prevalence and intensity levels were achieved among school-age children regardless of the treatment approach used.

1. Introduction

Schistosomiasis remains one of the most important water-based diseases in the world, with an estimated 247 million people infected in 74 countries, 85% of whom are living in sub-Saharan Africa (World Health Organization, 1993, 2002; Chan et al., 1994; Chitsulo et al., 2000). In Kenya, over 6.14 million people are estimated to have schistosomiasis with the highest infection rates found in adolescents (Grzych et al., 1987; Karanja et al., 1997, 1998). Overall, the prevalence of schistosomiasis in endemic areas of Kenya ranges from 5% to 100%, contributes to significant morbidity (Ouma et al., 2001; Mwinzi et al., 2004; Odiere et al., 2012; Samuels et al., 2012) and is very high along the shores of Lake Victoria (Handzel et al., 2003; Standley et al., 2010). Morbidity associated with schistosomiasis includes under-nutrition, anaemia, chronic pain, diarrhea, exercise intolerance, growth stunting and cognitive impairment (Booth and Bundy, 1992; Stephenson et al., 2000). Much of the morbidity is reversible and can be controlled with treatment using praziquantel (PZQ) (Taylor-Robinson et al., 2007; Keiser and Utzinger, 2008).

Prevalence and intensity of infection are the key indicators currently used to measure the burden of schistosome infection in a given community. The number of eggs per gram (EPG) of feces provides a relative measure of infection intensity and is a key indicator of transmission dynamics within communities as well as the risk of morbidity among individuals (Anderson and May, 1985). Assessment of infection intensity requires quantitative laboratory methods that are time consuming. Prevalence of infection is the more easily collected indicator and is used by the World Health Organization (WHO) to provide guidelines for scope and frequency of mass treatment with PZQ (World Health Organization, 2013). PZQ is an effective, safe, single-dose treatment for schistosomiasis with few adverse events in uninfected individuals, making it appropriate for mass drug administration (MDA) for schistosomiasis control (Danso-Appiah et al., 2008).

In 2001, the 54th World Health Assembly endorsed resolution 54.19 to promote preventive measures, ensure treatment and mobilize resources for the control of schistosomiasis and soil-transmitted helminths (STHs) (Kabatereine et al., 2006). This

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resolution helped to increase interest from global sponsors and governments in endemic regions to control schistosomiasis and other neglected tropical diseases (NTDs) and to establish national action plans. Examples include Uganda and Tanzania in 2003 (Guyatt et al., 2001; Kabatereine et al., 2006, 2007). In these countries, the main strategy for the delivery of anthelmintics was through the school system, an approach that reduces both infection and morbidity in a cost-effective manner as well as enhances educational outcomes in the treatment area (Guyatt et al., 2001; Miguel and Kremer, 2004; Kabatereine et al., 2007). However, treating only school children leaves out other members in the community who are also at risk of morbidity from infection and who could contribute to continued transmission. This includes out-of-school children, older children and adults as well as occupationally-exposed groups like car washers, sand harvesters, fishermen and fish handlers (Webbe and El Hak, 1990; Karanja et al., 1997, 1998).

To also provide treatment for these groups, a community-based approach, where all members of the community are targeted for treatment, could be used. A multi-country study on community directed intervention (CDI) for onchocerciasis control demonstrated that community-based drug distribution can be effective and feasible for integrated delivery of different health interventions in rural Africa (Massa et al., 2009a,b). However, direct comparison studies of school and community based approaches or combination strategies in different settings have not been performed, particularly in Kenya. Data are needed to inform the most effective control strategies and provide evidence for the most cost efficient deworming frequencies, for example, how often MDA should be conducted.

It is in this context that we are working with the Schistosomiasis Consortium for Operational Research and Evaluation (SCORE) to evaluate different MDA approaches with PZQ in areas of western Kenya with high prevalence ($\geqslant$25%) of *Schistosoma mansoni* infections in school age children. In a 5 year study, PZQ is delivered either through school-based treatment (SBT) or community-wide treatment (CWT). The two approaches involve regimens of drug treatment with varying treatment frequency. We report changes in *S. mansoni* prevalence and egg intensity levels after two rounds of MDA with reported treatment coverage rates. From the experience of two rounds of MDA, we also gained insight on how to improve MDA delivery.

2. Materials and methods

2.1. Study site, population and design

This study was conducted in eight districts in Nyanza province stretching approximately 300 km along the Kenyan shores of Lake Victoria. A total of 150 villages lying within 5 km of the lake shore were enrolled. Over 96% of the population in the study area are members of the Luo community. Although fishing is the main commercial activity in the villages, the majority of the residents are subsistence farmers. All residents in the area are at risk of infection with schistosomiasis due to frequent water contact in Lake Victoria. No PZQ MDA activities had been conducted in the area prior to 2011 when the study was initiated as the Kenya national program had yet to implement PZQ distribution. However, one albendazole MDA for STHs had been conducted in 2009.

Following an eligibility survey of 13–14 year olds to identify villages with $\geqslant$25% prevalence, 150 communities were selected and randomised into one of six study arms, 25 villages per arm (Fig. 1). In arms 1–3 (CWT), community health workers (CHWs) were used to distribute drugs by going house-to-house each year during April, which is the school vacation period when students are most likely to be at home. CHWs provided PZQ for all persons who were eligible (>4 years of age and/or >94 cm tall). For persons who were present in the home, CHWs directly observed treatment. For persons who were not at home, the appropriate number of tablets were left. In arms 4–6 (SBT), health teachers were engaged to deliver PZQ to the children during February and March of each year and directly observed the students swallowing the treatment. Efforts were made to invite school age children who were not attending school to also participate in the MDA.

2.2. Study approval and involvement

The study was reviewed and approved by the National Scientific and Ethical Review Committees (ERC) of the Kenya Medical Research Institute (KEMRI) and the Institutional Review Board of the Centers for Disease Control and Prevention, USA, which deferred to the KEMRI ERC. Permission to conduct the study was obtained from the Ministry of Education, Ministry of Public Health and Sanitation and the Nyanza Provincial Administration, Kenya. Sensitisation of community members and school teachers was conducted to explain the purpose of the study and to gain support to test school children and adults in the community. CHWs and school health teachers were invited to training workshops where they were instructed in the collection of stool, use of the treatment dose pole, how to maintain drug administration records, and how to recognise serious adverse events (SAEs) associated with treatment. Consent documents and participation information were provided to potential participants in the language they understood best (English or Dholuo). Consent and assent for study participation and treatment were obtained from the parents or guardians and from the children, respectively.

2.3. Parasitological assessment

For the baseline assessment, 100 randomly selected 9–12 year old pupils and 100 first year students (children attending their first year of schooling) in each village were requested to provide stool samples. The 9–12 year olds provided three stool samples on three consecutive days while the first year students provided only one stool sample. In each community, 50 adults were randomly selected and, following enrollment and informed consent, asked to provide one stool sample. A greater number of samples were obtained from 9 to 12 year olds because the main goal of the study was to assess the impact of different MDA strategies on this age group. Sampling of first year students was performed to test if the MDA approaches had different impacts on the force of transmission and adults were sampled to monitor for any global changes that may be affecting the study village. However, as these were secondary questions and resources were limited, only one stool sample was collected from first year students and adults. Similarly, while stool samples were obtained from 9 to 12 year old students every year, according to the harmonised SCORE protocol, first year student and adult samples were only scheduled for the first (baseline), third (after two treatments), and fifth (after four treatments) years of the study. Each participant was issued empty stool cups and other sanitary necessities such as tissue paper and a scoop-stick, and the procedure for safe stool collection was explained. Stool sample collection took place over the course of 1 week in any one school or community by a team of one to two technicians with the help of a health teacher or CHW.

Stool samples were then transported to laboratories at KEMRI Center for Global Health Research (KEMRI-CGHR) and the Ministry of Health's Division of Vector-Borne Diseases (DVBD) laboratory, Kisumu, where they were processed. Each stool sample was analyzed in duplicate by the Kato–Katz technique for eggs of *S. mansoni*, *Ascaris lumbricoides* and *Trichuris trichiura* by

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