

Cote d'Ivoire Impact Survey 2017

Measuring *control of morbidity* in schistosomiasis and soil transmitted helminthiasis with preventive chemotherapy







Imperial College London



Contents

| Introduction | 4 |
|--|----|
| Background to the Impact Survey | 4 |
| Schistosomiasis and soil-transmitted helminthiasis | 4 |
| Schistosomiasis and STH in Cote d'Ivoire | 4 |
| Aim | 5 |
| Ethical approval | 5 |
| Objectives | 5 |
| Study Design | 5 |
| Overview | 5 |
| Study Outcomes | 6 |
| Timing of survey | 7 |
| Study Setting | 7 |
| Number of schools to survey | 7 |
| Type of schools to survey | 9 |
| Selection of schools to survey | 9 |
| What to do if a school cannot be visited | 9 |
| Selection of children to sample within each school | 9 |
| Data collection and analysis | 10 |
| APPENDIX A: Field team planning manual | 11 |
| Survey team composition | 11 |
| Survey team training | 11 |
| Timetable of activities | 11 |
| Roles and responsibilities | 12 |
| APPENDIX B: Data Collection Protocol & Standardised Operating Procedures | 14 |
| Phase II Follow-Up 1 (FU1) & Phase I Follow-Up 2 (FU2): DATA COLLECTION PROTOCOL | 14 |
| Before arriving at the school | 14 |
| Arriving at the school | 14 |
| Obtaining Consent | 14 |
| Child Assent Form | 17 |
| What to do if there are not enough students in any age/sex group | 20 |
| Collecting the samples | 20 |
| Treatment in schools involved in monitoring process | 21 |
| Kato Katz SOP | 22 |
| Haemastix SOP | 26 |



| Urine Filtration SOP | 28 |
|--|----|
| APPENDIX C: Data Collection Forms | 31 |
| Form 1: School Information Form notes | 34 |
| Section A: Site Details | 34 |
| Section B: GPS | 34 |
| Section C: School Details | 34 |
| Section D: Enrolment Numbers | 35 |
| Form 3: Individual Form notes | 45 |
| A. Individual Details | 45 |
| B. WASH Questions | 45 |
| Form 3: Individual Form | 45 |
| A. Individual | 45 |
| B: Kato Katz | 46 |
| C Urine Filtration and Dipstick Result | 46 |
| Form 4: WASH Form | 47 |
| Appendix C: Detailed survey methodology & sample size estimation | 48 |
| Deviations from SCI principles in this protocol | 48 |
| Sample size details | 48 |
| Statistical approach to impact surveys | 48 |
| References | 51 |



Introduction

This survey protocol describes the background and implementation design for the impact survey that will be conducted in Cote d'Ivoire in October 2017. Mapping was conducted in 2012 by Cote d'Ivoire's Ministry of Health (MoH) which has informed the strategy for the implementation of the preventive chemotherapy (PC) programme for schistosomiasis (SCH) and soil transmitted helminth infections (STH). The aim of this impact survey is to evaluate the effectiveness of PC in reducing baseline parasitological indicators of infection.

Background to the Impact Survey

Schistosomiasis and soil-transmitted helminthiasis

Schistosomiasis or Bilharzia is a parasitic disease caused by infection with the trematode blood-flukes schistosomes. In sub-Saharan Africa, two major forms of human schistosomiasis occur: intestinal schistosomiasis caused by mainly *Schistosoma mansoni* infection and urogenital schistosomiasis due to *Schistosoma haematobium* infection. Soil-transmitted helminthiasis is caused by infection with a group of intestinal nematode worms, most important of which within much of sub-Saharan Africa are the hookworms (both *Ancylostoma duodenale* and *Necator americanus*), the roundworm (*Ascaris lumbricoides*) and whipworm (*Trichuris trichiura*). Both schistosomiasis and STH are among the neglected tropical diseases (NTDs), which remain serious public health problems, posing unacceptable threats to human health and welfare.

The World Health Assembly resolution 54.19 urges all member states to regularly treat at least 75% of all school aged children who are at risk of morbidity from schistosomiasis and STH. The current control strategy recommended by the World Health Organization is to control the morbidity caused by these parasitic infections through PC with Praziquantel (PZQ) for SCH and Albendazole or Mebendazole (ALB or MBZ) for STH infection. Schistosome morbidity is mainly caused by the eggs deposited in various parts of the body depending on the species of schistosome, hence the fundamental aim of morbidity control is to reduce prevalence and intensity of infection by drug treatment.

Schistosomiasis and STH in Cote d'Ivoire

The Programme National de Lutte contre les Maladies Tropicales Négligées à Chimiothérapie Préventive (PNLMTN-CP) was established in 2007 and takes on the role of leadership and coordinating activities of all the partners and stakeholders involved in the fight against SCH, STH and lymphatic filariasis (LF). Emphasis is placed on the activities demonstrating large reduction in morbidity and mortality associated with these infections.

SCH is endemic in 81 districts out of 83 districts and STH is endemic in 82 districts. The mapping was done in 2012 and in October 2016 the programme achieved national coverage of PC for all endemic districts. The mass drug administration (MDA) in 2017-2018 will take place in 39 districts in November 2017.



Aim

This survey protocol is designed to monitor the impact of PC with PZQ and ALB/MEB on the prevalence, intensity and morbidity of SCH and STH infection in SAC during the *Control of Morbidity* phase with the aim of reaching less than 5% heavy intensity of infection across sentinel sites¹.

Ethical approval

An application for ethical approval at the University Felix Houphouet-Boigny was submitted. The approval document can be found here:

https://imperiallondon.sharepoint.com/:b:/r/sites/fom/schisto/mer/2 Country M%26E/CIV/Impact /FY 1718/1 Protocol %26 pre-survey/CIV Ethical approval Sentinel Sites.pdf?csf=1&e=bs5OhY

Impact surveys have been granted ethical approval in the UK by Imperial College Research Ethics Committee (ref: ICREC_8_2_2).

Objectives

The objectives of the impact survey are:

Survey Objective (SO)

SO 1. To measure the prevalence of SCH in SAC over time

SO 2. To measure the mean intensity of SCH in SAC over time

SO 3. To measure the percentage of heavily infected SAC with SCH over time

SO 4. To measure the prevalence of STH in SAC over time

SO 5. To measure mean intensity of infection of STH over time

SO 6. To measure the percentage of heavily infected children with STH over time

- SO 7. To measure macro haematuria in children with S. haematobium infection over time
- SO 8. To measure micro haematuria in children with S. haematobium infection over time

SO 9. To determine demographic and school information

SO 10. To measure Water, Sanitation and Hygiene (WASH) indicators

Study Design

Overview

The observational epidemiological surveys will be used to establish an association between infection status and treatment over time through the national PC programme for SCH and STH. The surveys will use a cross-sectional design whereby a new selection of children from the same age groups will be randomly sampled from the same sentinel schools each year of the survey (minimum 3 years). See Appendix C for a detailed explanation of the statistical approach to the impact surveys, including why cross-sectional sampling was chosen for this survey.

¹ WHO target for control of morbidity phase (5 to 10 years from inception of treatment) in the progress towards schistosomiasis elimination (WHO, 2013)



Study Outcomes

The following outcomes will be measured:

- *S. haematobium*: eggs per 10ml of urine using urine filtration method (1 slide per day, repeated over 1 day)
- *S. mansoni*: eggs per 1/24th gram of faeces² using the Kato-Katz method (2 slides per day, repeated over 2 days)
- Ancylostoma duodenale, Necator americanus³: eggs per 1/24th gram of faeces using the Kato-Katz method (2 slides per day, repeated over 2 days)
- Ascaris lumbricoides: eggs per 1/24th gram of faeces using the Kato-Katz method (2 slides per day, repeated over 2 days)
- *Trichuris trichiura*: presence of eggs; eggs per 1/24th gram of faeces using the Kato-Katz method (2 slides per day, repeated over 2 days)
- Macrohaematuria: Number of children with visible blood in urine i.e. direct observation of a urine specimen which appears reddish in colour
- Microhaeamturia: Number of children with micro haematuria as detected with a reagent dipstick
- Age, how long lived in the area, and sex
- Water, sanitation and hygiene questions⁴
- School information

| Parasitological Indicators | | | | |
|---|---|---|---|--|
| Parasite group | Prevalence of infection (%) | Intensity of infection (mean number of eggs) | Prevalence of intensity of infection (% of SAC within each category) | |
| S. haematobium (by urine filtration) | Number of infected SAC / total number of SAC examined | Average number of eggs per 10 ml of urine | <i>Low</i> : 1 to 49 eggs/10 ml urine <i>Heavy</i> : ≥ 50 eggs/10 ml urine | |
| S. mansoni (by Kato-Katz) | As above | Average number of eggs per gram of stool | Low: 1 to 99 eggs per gram (epg) Moderate: 100 to 399 epg Heavy: ≥ 400 epg | |
| Hookworms | As above | Average number of eggs per gram of stool | <i>Low</i> : 1 to 1,999 epg <i>Moderate</i> : 2,000 to 3,999 epg <i>Heavy</i> : ≥ 4,000 epg | |
| A. lumbricoides | As above | Average number of eggs per gram of stool | <i>Low</i> : 1 to 4,999 epg <i>Moderate</i> : 5,000 to 49,999 epg <i>Heavy</i> : ≥ 50,000 | |
| T. trichura | As above | Average number of eggs per gram of stool | <i>Low</i> : 10 to 999 epg <i>Moderate</i> : 1,000 to 9,999 epg <i>Heavy</i> : ≥ 10,000 epg | |

The following indicators will be calculated from the measured outcomes:

² Kato-Katz (KK) is a specific and sensitive tool to diagnose prevalence and intensity of *S. mansoni* infection to use in countries which are in the *control of morbidity* phase. CCA will be used, with a subset of KK, in countries in the *elimination as a public health problem* phase as it is more sensitive in low prevalence areas

³ *A. duodenale* and *N. americanus* (hookworm) need not be monitored where it presents logistical demands if mapping results have shown it to be prevalent at very low frequency.

⁴ Waite RC *et. al.* (2017)



Timing of survey

The impact survey will be within one month prior to the PC campaign with PZQ and ALB/MEB in November 2017.

Study Setting

This survey will sample SCH endemic schools which were randomly selected from high and moderate risk SCH communities from the districts which were treatment naïve at baseline⁵. The survey will be a Phase II Follow-Up 1 (FU1) and Phase I Follow-Up 2 (FU2) dependent on the number of rounds of treatment delivered through the programme. From the baseline mapping survey endemic districts were classified into a WHO recommended risk category (WHO, 2011). WHO guidelines state that high-risk communities (\geq 50% prevalence) for SCH should receive annual treatment and moderate risk communities (\geq 10% and <50% prevalence) for SCH, treatment every two years. The frequency of treatment is determined by the highest level of risk from either of the schistosomiasis species.

STH are treated according to the WHO guidelines (WHO, 2011) and are planned with consideration of other STH treatment in the country i.e. child health days and LF elimination programme.

Number of schools to survey

Per the baseline protocol (2013):

"For the selection of the sample size, we followed WHO recommendations and used one site for all of the 200,000 to 300,000 children targeted. To obtain a good representation of the population, it is suggested that 120 students be sampled per school.

It is suggested that this sample of 120 students per school be distributed equally between the four classes (CP1, CP2, CE1 and CM2): a minimum of 30 from CP1, 30 from CP2, 30 from CE1 and 30 from CM2, totalling 120 students (with an equal number of girls and boys per class), which is sufficient."

This has resulted in 26 schools required for Phase I and 11 schools for Phase II.

⁵ Naïve in terms of never having received national/large-scale treatment at the implementation unit level or with no treatment at then implementation unit for 3 years.



Table 1: Summary of mapping results for Cote d'Ivoire.

| | Number of schools | | Drouglance (%) of | r | Drouglance (%) of | Т |
|--|------------------------------|---|--|---------------------|--|----------------------------|
| District | Number of schools sampled | Endemicity of Sm/Sh | Prevalence (%) of S.mansoni (95%Cl) | Endemicity of Sm | Prevalence (%) of S.haematobium (95%Cl) | Endemicity of Sh |
| ABENGOUROU | 15 | average /non-endemic | 5.84 (2.12 - 15.08) | average | 0 (0 -0) | non-endemic |
| ABOBO EST | 15 | weak /weak | 1.97 (0.94 - 4.06) | weak | 0.66 (0.17 -2.52) | weak |
| ABOBO OUEST | 15 | weak /weak | 0.88 (0.3 - 2.55) | weak | 0.66 (0.24 -1.79) | weak |
| ABOISSO | 20 | average /weak | 17.33 (8.65 - 31.71) | average | 1.03 (0.53 -1.98) | weak |
| | 20 | weak /weak | 0.46 (0.18 - 1.15) | weak | 0.35 (0.12 -1.05) | weak |
| ADJAME PLATEAU ATTECOUBE AGNIBILEKROU | 15 15 | weak /weak weak /weak | 3.9 (1.53 - 9.59) 4.63 (2.18 - 9.57) | weak weak | 0.43 (0.12 -1.53) 0.66 (0.24 -1.79) | weak weak |
| ANYAMA | 15 | weak/weak | 3.49 (1.63 - 7.33) | weak | 2.9 (1.35 -6.11) | weak |
| BEOUMI | 20 | weak /weak | 0.67 (0.22 - 2.01) | weak | 2.68 (0.98 -7.1) | weak |
| BETTIE | 15 | weak /weak | 0.88 (0.21 - 3.69) | weak | 0.66 (0.24 -1.79) | weak |
| BLOLEQUIN | 15 | average /weak | 27.41 (16.61 - 41.72) | average | 0.44 (0.07 -2.81) | weak |
| BOCANDA | 15 | weak /weak | 2.27 (0.89 - 5.64) | weak | 0.21 (0.03 -1.34) | weak |
| BONDOUKOU BONGOUANOU | 15 15 | weak /weak weak /weak | 0 (0 - 0) 0.43 (0.07 - 2.79) | weak weak | 1.11 (0.39 -3.14) 3.69 (1.45 -9.09) | weak weak |
| BOUAFLE | 20 | non-endemic /weak | 0 (0 - 0) | non-endemic | 5.29 (3.54 -7.82) | weak |
| BOUAKE NORD-EST | 20 | non-endemic/weak | 0 (0 - 0) | non-endemic | 1.78 (0.84 -3.75) | weak |
| BOUAKE NORD-OUEST | 20 | average /weak | 5.33 (1.86 - 14.35) | average | 4.22 (2.48 -7.09) | weak |
| BOUAKE SUD | 20 | weak /weak | 0.53 (0.17 - 1.62) | weak | 2.11 (0.98 -4.45) | weak |
| BOUNA | 15 | weak /average | 0.87 (0.29 - 2.54) | weak | 7.59 (4.39 -12.8) | average |
| | 15 | weak /non-endemic | 1.04 (0.32 - 3.37) | weak | 0 (0 -0) | non-endemic |
| COCODY-BINGERVILLE DABAKALA | 15 20 | weak /non-endemic weak /weak | 0.43 (0.12 - 1.54) 0.1 (0.01 - 0.63) | weak weak | 0 (0 -0) 1.08 (0.38 -3.03) | non-endemic weak |
| DABANALA | 15 | weak /weak | 1.5 (0.64 - 3.49) | weak | 1.93 (0.64 -5.67) | weak |
| DAOUKRO | 15 | weak/weak | 1.76 (0.82 - 3.73) | weak | 5.51 (1.19 -22) | average |
| DIDIEVI | 15 | weak /average | 0.22 (0.03 - 1.42) | weak | 4.63 (1.98 -10.44) | average |
| DIMBOKRO | 15 | weak /average | 2.07 (1.01 - 4.18) | weak | 6.82 (2.96 -14.91) | average |
| DIVO | 20 | average /average | 5.25 (1.63 - 15.67) | average | 19.87 (13.66 - 27.99) | average |
| FERKESSEDOUGOU FRESCO | 15 15 | weak /weak average /weak | 0.42 (0.12 - 1.52) 6.15 (3.41 - 10.85) | weak average | 0.64 (0.23 -1.74) 4.4 (1.93 -9.68) | weak weak |
| GAGNOA | 20 | average / weak | 10.83 (8.07 - 14.39) | average | 6.18 (4.26 -8.87) | weak |
| GRAND-BASSAM | 20 | weak /weak | 1 (0.27 - 3.63) | weak | 0.67 (0.22 -2.01) | weak |
| GRAND-LAHOU | 15 | weak /weak | 2.55 (1.09 - 5.85) | weak | 1.07 (0.43 -2.61) | weak |
| GUEYO | 20 | average /weak | 8.56 (4.63 - 15.29) | average | 2.7 (1.62 -4.47) | weak |
| ISSIA | 15 | average /average | 11.8 (5.13 - 24.87) | average | 10.77 (5.79 -19.15) | average |
| JACQUEVILLE KATIOLA | 15 19 | weak /weak | 0.43 (0.07 - 2.73) | weak | 0.43 (0.12 -1.52) | weak |
| KORHOGO | 19 | average /average weak /weak | 5.94 (1.75 - 18.3) 5.65 (4.03 - 7.86) | average weak | 10.41 (6.18 -16.99) 0.42 (0.12 -1.49) | average weak |
| KOUMASSI PORT-BOUET VRIDI | 15 | weak/weak | 0.87 (0.13 - 5.45) | weak | 0.22 (0.03 -1.41) | weak |
| LAKOTA | 20 | average /average | 2.54 (0.81 - 7.63) | average | 14.55 (7.33 -26.84) | average |
| M'BAHIAKRO | 15 | weak /average | 0.58 (0.21 - 1.57) | weak | 6.98 (2.09 -20.85) | average |
| MANKONO | 15 | weak /weak | 2.51 (1.22 - 5.09) | weak | 1.26 (0.35 -4.43) | weak |
| MARCORY - TREICHVILLE | 15 | weak /weak | 0.44 (0.07 - 2.81) | weak | 0.44 (0.12 -1.56) | weak |
| MINIGNAN NASSIAN | 15 15 | weak /weak weak /weak | 1.33 (0.44 - 3.96) 0 (0 - 0) | weak weak | 0.89 (0.3 -2.59) 0 (0 -0) | weak weak |
| NIAKARA | 20 | weak/weak | 0.19 (0.03 - 1.27) | weak | 0.53 (0.25 -1.13) | weak |
| ODIENNE | 15 | weak /average | 2.67 (0.95 - 7.29) | weak | 3.78 (0.56 -21.56) | average |
| OUANGOLODOUGOU | 15 | weak /weak | 0.21 (0.03 - 1.37) | weak | 3.37 (1.22 -8.93) | weak |
| OUME | 20 | weak /weak | 4.17 (2.55 - 6.77) | weak | 5.68 (3.6 -8.85) | weak |
| PRIKRO | 15 | average /weak | 4.11 (1.03 - 15.06) | average | 0.22 (0.03 -1.4) | weak |
| SAKASSOU SAN-PEDRO | 20 20 | weak /average average /weak | 0.5 (0.18 - 1.4) 4.99 (2.01 - 11.86) | weak average | 11.22 (6.62 -18.39) 4.59 (2.77 -7.52) | average weak |
| SASSANDRA | 20 | average / weak | 4.99 (2.01 - 11.88) 8.51 (4.23 - 16.39) | average | 2.68 (1.14 -6.2) | weak |
| SEGUELA | 15 | weak /weak | 1.05 (0.5 - 2.16) | weak | 1.47 (0.37 -5.58) | weak |
| SIKENSI | 15 | average /average | 5.38 (2.83 - 9.97) | average | 10.78 (5.1 -21.36) | average |
| SINFRA | 15 | weak /average | 0.62 (0.23 - 1.68) | weak | 9.96 (5.89 -16.34) | average |
| SOUBRE | 20 | average /average | 28.17 (21.06 - 36.56) | average | 8.67 (5.99 -12.38) | average |
| TABOU | 20 | average /weak non-endemic /non-endemic | 6.02 (3.43 - 10.36) | average | 0.5 (0.2 -1.27) | weak |
| TANDA TENGRELA | 15 15 | weak /non-endemic | 0 (0 - 0) 1.48 (0.62 - 3.48) | non-endemic weak | 0 (0 -0) 0 (0 -0) | non-endemic non-endemic |
| TIEBISSOU | 20 | weak /average | 4.6 (3.6 - 5.87) | weak | 17.26 (10.06 -28) | average |
| TOUBA | 15 | forte /weak | 39.55 (25.46 - 55.62) | forte | 1.43 (0.6 - 3.38) | weak |
| TOULEPLEU | 15 | average /weak | 29.05 (17.94 - 43.39) | average | 0.22 (0.03 -1.43) | weak |
| TOUMODI | 15 | weak /average | 1.11 (0.45 - 2.69) | weak | 15.93 (6.96 -32.41) | average |
| VAVOUA | 15 | weak /weak | 0.41 (0.11 - 1.46) | weak | 1.02 (0.41 -2.5) | weak |
| VANOUCCOURDO | 20 | weak /average | 2.93 (1.14 - 7.33) | weak | 13.79 (7.06 -25.17) | average |
| YAMOUSSOUKRO | 15 | sugarba di di di di | 24/4 20 7 22 | | 4 44 (0 45 0 60) | |
| YOPOUGON EST YOPOUGON OUEST - SONGON | 15 15 | weak /weak weak /weak | 3.1 (1.29 - 7.23) 0.67 (0.24 - 1.8) | weak weak | 1.11 (0.45 -2.69) 0.22 (0.03 -1.43) | weak weak |

• Mapping data for the 14 missing districts was created prior to the ICOSA program and was reported in scientific journals.



Type of schools to survey

The surveys will be conducted in primary schools for a number of reasons, including:

- Higher primary school enrolment in Cote d'Ivoire (78.9%) ensures that the majority of children of the desired age group will be included in the sampling frame, minimising selection bias
- Primary schools present a convenient platform for conducting surveys and delivering treatment to the greatest at-risk individuals
- Infection levels in older primary school children are thought to be an accurate measure of overall infection in the wider community.

Selection of schools to survey

Sentinel schools will be randomly selected from the treatment naïve districts in high and moderate risk SCH communities. The sampling frame will be the list of schools within this population so that all schools have the opportunity to be selected. The sampling will be stratified by risk category for each schistosomiasis species to ensure a balance of schools across the different prevalence categories of schistosomiasis. See Appendix C for full details of stratification and site selection.

What to do if a school cannot be visited

A short list of 'reserve schools' will be provided, such that if a selected school cannot be visited for security or other unpredictable reasons, it can be replaced with another in the same district. Note that selected school should only be replaced with those on the reserve list in extreme circumstances where it is impossible to survey that school, and not for reasons of distance, access difficulty and so on. It is important to document in the field report any school that have been replaced and the reason for this replacement, as this could be a reason for biased impact results.

Selection of children to sample within each school

A total of 120 students will be sampled per school. The SCI protocol is for the ages equating to the highest four grades in primary school to be sampled in equal numbers, as schistosomiasis prevalence generally increases with age in childhood. In Cote d'Ivoire, the majority of schools begin in CP1 at 6 years old with children completing at CM2 at 11 years old. Consequently, we will sample ages 6, 7, 8 and 11, with 30 children (50% male, 50% female) being sampled from each age group in each school (see Table 2). For details of sample size calculations, please see Appendix C.

It is suggested that this sample of 120 students per school be distributed equally between the four classes (CP1, CP2, CE1 and CM2): a minimum of 30 from CP1, 30 from CP2, 30 from CE1 and 30 from CM2, totalling 120 students (with an equal number of girls and boys per class), which is sufficient.



| Year | Age in | cross sectional st | tudy | |
|-------------|--------|--------------------|------|----|
| Baseline | 6 | 7 | 8 | 11 |
| Follow-up 1 | 6 | 7 | 8 | 11 |
| Follow-up 2 | 6 | 7 | 8 | 11 |
| Follow-up 3 | 6 | 7 | 8 | 11 |

Table 2. Age groups of children to be sampled

Data collection and analysis

Paper data collection forms and a double entry system into an excel database for this impact survey will be used. Appendix B contains the school detail form and pupil case record form. Once data has been double entered and cleaned in-country, a copy should be sent to the SCI biostatistician whereupon it will be analysed in conjunction with the in-country stats or technical team, for the specific indicators listed above. If capacity building is required in-country to increase skills in data management and analysis, SCI will tailor a training package based on requests by the MoH. All analyses will be fully shared with collaborators in-country, and the original database will remain with the Ministry of Health.



APPENDIX A: Field team planning manual

Survey team composition

- The teams are from the University Felix Houphouët-Boigny
- There will be 4 teams going to 14 districts in total
- Each team is composed of 5 members (one supervisor, three technicians, one driver)
- The duration of the survey is expected to be 3 weeks

Survey team training

The training will be done by Professor Elezier N'Goran and will give a presentation to all team members going on the field. The training will take place at the University Felix Houphouet-Boigny. The training will be done in the fields (2 days) with all parasitologists. The activities will start in October 2017 for a duration of 3 weeks.

The training will cover the following aspects:

- Rationale and background for conducting the mapping survey
- Essential aspects to maintain unbiased data collection
- Setting up laboratories
- Filling in WASH, school and individual forms
- Health and safety when handling samples
- How to use the microscope
- Preparation of samples: kato-katz, urine filtration and hemastix
- Identification and counting of parasite eggs
- Cleaning up procedures
- Data entry by two clerks (team members) to be checked by the team leader

Timetable of activities

The activities will start in October 2017 for a duration of 3 weeks in 14 districts.

| Districts | Name of sentinel site | Number of sentinel sites |
|--------------|---|--------------------------|
| Abengourou | EPP Yakasse 1 | 1 |
| Aboisso | EPP Kohourou 1 / EPP Soubre | 2 |
| Bloléquin | EPP Yoya Goya | 1 |
| Daoukro | EPP Ouelle-Plateau | 1 |
| Dimbokro | EPP Est 1 /EPP Plateau 2 | 2 |
| Issia | EPP Issia 2 Sud B | 1 |
| Katiola | EPP Kabolo &EPP Timbe / EPP Nahobankaha & EPP Lougbonou 1 | 4 |
| Mbahiakro | EPP Bedara | 1 |
| Odienné | EPP Kongohila | 1 |
| Prikro | EPP Groumania | 1 |
| Sakassou | EPP Attiakro / EPP Toumodi-Sakassou 2/ EPP Konan Moukro & EPP Kangre | 4 |
| Tiébissou | EPP Bondoukou / EPP Mamadou Koffi 2 | 2 |
| Touba | EPP Koro 1 | 1 |
| Yamoussoukro | EPP Labokro 1 / EPP Kossou 1 | 2 |



Roles and responsibilities

The survey team will be formed by the following team members: (choose from the following list or add other categories as required)

- Programme Manager (PM); primary duties:
 - Adapt and finalise the survey protocol (with in-country programme manager and SCI biostatistician)
 - o Obtain SCI sign-off of protocol
 - Obtain necessary ethical approvals (with the Ministry of Health)
 - Identify the survey team*
 - Organise survey logistics*
 - Train and supervise the survey team*
 - Oversee the data entry*
 - \circ Write the final survey report (with in-country programme manager and SCI biostatistician)
 - *Together with in-country programme manager
- In-country programme manager = Survey coordinator
 - Adapt and finalise the survey protocol (together with the SCI program manager and biostatistician)
 - If necessary, arrange translation and back translation information sheet and consent form in local languages
 - Identify the survey team**
 - Organise the survey logistics**
 - Train the survey team**
 - Oversee the data entry (paper or mobile-based)**
 - Lead one of the teams
 - **Together with SCI programme manager
- Team leader
 - \circ $\;$ Contact local schools in the survey area to advise them about the study
 - Ensure strict adherence to the survey protocol
 - Locate the schools and fill in the school form
 - o Randomly select the student according to this protocol
 - Provide the survey teams with necessary materials for daily activities
 - o Review surveys for accuracy and completeness after each school is done.
 - $\circ~$ Review collected data (and eventual upload of data if mobile-based) at the end of each day
 - Manage daily logistics
 - o Lead a daily debrief with the team
 - Provide the field report
- Team member
 - Set up the laboratory equipment in each school
 - Report any issues or concerns to the team leader as they occur
 - Understand the sampling protocol and the necessity of protocol compliance
 - Help in the Team Leader in the process of selection of students
 - o Provide the students with container for stool and urine
 - \circ Collect the containers with stool and urine and process them to undertake the quantification of the parasitic load
 - Clear the laboratory at the end of the day



- Data entry personnel
 - $\circ~$ The data entry personnel must be knowledgeable of data management and data entry.
 - Two persons should enter the same data into different spreadsheets and send it to the team leader for him to check any inconsistencies
- SCI Biostatistician
 - Together with the survey coordinator and SCI program manager, adapt and finalise the survey protocol
 - Determine the sampling strategy and number schools and children per school to be surveyed
 - Select the schools to sample
 - $\circ \quad \text{Clean the data} \quad$
 - \circ $\,$ $\,$ Analyse the data and produce the report graphs and tables with SCI PM $\,$
 - Write the data cleaning notes in the report



APPENDIX B: Data Collection Protocol & Standardised Operating Procedures

Phase II Follow-Up 1 (FU1) & Phase I Follow-Up 2 (FU2): DATA COLLECTION PROTOCOL

Before arriving at the school

The school should be notified of the survey at least one week before the survey is due to start.

• When contacting the state, the purpose of the survey and a list of equipment that you need (e.g. tables and chairs) to allow for quick start

Preparations should be made for the survey before arriving at the school:

- Pre-fill pupil identification numbers on the registration forms and slides
- Ensure all equipment is organised
 - o Dipsticks cut
 - Cellophane soaking in methyl blue
 - o Plastic cut
 - o Urine filter holders filled

Arriving at the school

The first thing the team should do when arriving at the school is to seek out the head teacher:

- 1. Introduce the team and ask for permission to survey
- 2. The team leader should obtain written permission from the head teacher to survey using the 'head teacher consent form' (appendix B)
- 3. The team leader should interview the head teacher to complete the 'school information form' and the 'school wash form' (appendix B)
- 4. The **GPS coordinates** of the school should be entered on **arrival and departure** if data is being collected on paper forms

Obtaining Consent

Parents/guardians of children at the school will also be informed of the study through school meetings with the director/head teacher and be requested to provide written informed consent for their children to participate within the study. Children over 10 years will be invited to give their assent in addition to parental consent. Where requested by parents, an additional meeting with the technical survey staff can be arranged where more detailed information as to why the study is taking place and questions answered by technical staff.



Newsletter For Obtaining Consent

Project title:

<u>ICOSA Ivory Coast</u>: Follow-up and national evaluation study of Soil-transmitted Schistosomiasis and Helminths in Ivory Coast

Persons responsible:

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Ms **Nadia Ben Meriem** (Co-PI), Programme Manager of the SCI program, Department of Infectious Diseases and Epidemiology, Impérial College, London (St Mary's Campus) ; <u>n.ben-meriem@imperial.ac.uk</u>

Humans can be parasitised by different types of worms. These worms are responsible for health problems such as diarrhoea, stomach ache, vomiting and loss of appetite. Moreover, infestations of intestinal worms can cause malnutrition and affect mental and physical development during childhood. Chemotherapy remains one of the main options for the fight against these parasites.

This study, also underway in many other countries, will focus on free mass treatment against bilharziasis and intestinal worms, and assess the impact of this treatment on the health of populations over the coming years.

The drug administered is Praziquantel, the only drug used everywhere against schistosomiasis. This drug is not dangerous for your health or that of your child. Like any medication against worms, it can produce discomfort, though this is not usually severe. However, doctors and nurses are on hand to help if you or your child feel ill.

The treatment will be free, and available to all children old enough to be at school, whether they attend or not. We want all children to participate by taking the drug, to increase the chances of eliminating the disease in your community.

Some students aged 6 to 11 in classes CP1, CP2, CE1 and CM2 will be asked to provide samples of faeces and urine for detection of parasites, to see whether their number decreases with treatment and time. Participation in the study is voluntary, and you may decide to withdraw yourself or your child at any time, with no consequences.

Other than those primarily responsible for the project, the results of your child's analyses will only be given to you or your child should you so request. For reasons of confidentiality, every child will be identified by a number, in order to avoid any link being established between test results and named individuals.



Parent / Legal Guardian Written Informed Consent for Child/Children Participation

| The stud | ly will b | oe condu | cted in 37 locati | ions spread over the whole c | ountry fromto |
|---------------------|------------------|-------------------------|---------------------------------------|---------------------------------|---|
| Name of | finterv | iewer: | | | Code No.: |
| Date | / | / | Place | Signature | |
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| | | | I have ha | d this document translated | |
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| written agree to | inform the po | ation. I a articipat | sked all of the q ion of myself ai | uestions I wished, and receiv | d the nature of the project and ved satisfactory answers. I freely hat myself and/or my child car ation. |
| Full nam | ne of th | e child : | | | |
| Date | / | _/ | Place | Signature(NB: for t | hose of legal age) |
| Full nam | e of th | e mothe | r or father: | | |
| Date | / | / | Place | Signature | |
| Or | | | | | |
| Full nam | ne of le | gal guaro | dian: | | |
| Date | / | / | Place | Signature | |
| Nonce | | | o alco a | | |
| ivame of | Health | n care w | orker: | | |
| Date | / | / | Place | Signature | |



Child Assent Form

(Intended for children over 10 years participating in the study)

Enter the identification number of the participant

Subject: Longitudinal cohort study for monitoring and national evaluation of Soil-transmitted Schistosomiasis and Helminths (STH) in Ivory Coast

| O I have read this |
|--|
| I have had the information form read and explained to me |
| I have understood the general objective of the project, procedures, and associated benefits and risks. |
| I received answers to all my questions. I also know I can withdraw at any time, without prejudice or |
| explanation. |
| |
| ○ I agree to participate in the study. |
| |
| |
| Date:/20 |
| Place: |
| |
| |
| |
| Signature of project health care worker |



Selecting the students

All students within a school that meet the required ages should be separated into age groups (6 year olds, 7 year olds, 8 year olds and 11 year olds) and assembled in separate lines – one line of boys and one line of girls for each age.

Exclusion criteria: Any child who is unwell (e.g. fever) should not take place in the study and be referred instead to the health workers. Any child whose parents have refused their child's participation in the study should not be included.

15 girls and 15 boys should be selected from each age group

If more than 15 students are present in an age/sex group, they should be selected randomly.

The steps to take for sampling pupils when there are more than 15 in an age/sex group are:

- 1. Count the total number of students in the line
- 2. Calculate the sampling fraction (*h*) using the equation below. Non-whole numbers should be rounded up.

$h = \frac{Total \ number \ of \ children \ in \ line}{15}$

- 3. Select the first child by randomly selecting a number between 1 and *h*. Random number selection can be done in the field by writing numbers on pieces of paper, folding them up, placing them in a container and mixing before drawing one out at random, and then selecting the child that is in this place in line.
- 4. The second child to sample should be the initial number + *h*.
- 5. Sampling should then proceed in this manner with every h^{th} child being sampled.
- 6. The selected children should be asked to leave the line to provide samples
- Sampling should start from be beginning again If the end of the line is reached before 15 pupils are selected. Pupils already selected from the beginning of the line should be excluded from the second selection

Example of selection of children when there are more than 15 children in the age/sex line:

- 1. There are 25 girls in the line.
- 2. Therefore h = 25/15 = 1.666, which is rounded up to 2
- The numbers 1 2 are written on pieces of paper, folded up and placed in a container and mixed up. The random piece of paper drawn out is 2.
- 4. The girl second in line is identified and asked to provide samples.
- 5. The second child to select for sampling is $2 + 2 = 4^{th}$ in line. The child fourth in line is identified, taken from the line, and asked to provide samples
- 6. Sampling then continues to children 6 (= 4 + 2), 8, 10, 12, 14, 16, 18, 20, 22, 24 until the end of the line is reached
- 7. Only 12 children have been selected so far so sampling needs to go back to the beginning of the line excluding children who have already been selected
- 8. The next child to be sampled is number 1 in line (24 + 2 = back to the first person in line)
- 9. The next child to be sampled is number 3 in line (1 + 2) now that selected people have been removed, but number 5 in the original line



10. The final child to be sampled in number 5 in the line with selected people removed (3+ 2 = 5) but number 7 in the original line



A list of the students selected to be in the survey should be given to the school for their records.



What to do if there are not enough students in any age/sex group

If there are less than 15 pupils in any of the desired age/sex groups within the sampled school, sample everybody in that age/sex group. Then 'top-up' the numbers with:

1. Children of the same sex who are in the age groups to be selected but haven't been selected for their age group

2. Children of the different sex who are in the age groups to be selected but haven't been selected for their age group

3. Children of the same sex who are one year younger than the minimum age targeted

4. Children of the different sex who are one year younger than the minimum age targeted

If there are still not enough pupils selected, then sample less than 120 pupils. **Do not sample ages outside the targeted ages and one year younger, and do not go to neighbouring schools to sample more children.** Make sure that the schools information form records the number of children in the school correctly.

Example of 'topping up' selection when there are less than 15 children in an age/sex group: If the targeted ages are 10-14 and there are less than 15 girls aged 14. Select:

- 1. Girls aged 10-13 who haven't been selected already
- 2. Boys aged 10-14 who haven't been selected already
- 3. Girls aged 9
- 4. Boys aged 9

Collecting the samples

- 1. Each selected student should be asked for verbal consent to provide urine and stool samples. Urine samples should be collected between 10am and 2pm.
- 2. Give the selected student empty stool and urine containers and instruct them how to collect sufficient amounts of urine and stool for testing.
- 3. The team leader registers the student, labels the specimens with an identification number and enters the child's personal details on the individual form (Appendix B).
- 4. The student submits the stool specimen to the "Kato-Katz" table and proceeds to the "urine" table where the urine sample is submitted.
- 5. A separate stool sample should be requested on the second day of the exercise.
- 6. All urine samples should be assessed for macro-haematuria, tested for micro-haematuria and be filtered to be examined for eggs, following the Standard Operating Procedures (SOPs) without deviation. Urine filtration should be done on all urine samples and not just those positive for micro-haematuria
- 7. All stool samples should be examined for eggs following the Standard Operating Procedures (SOPs) without deviation
- 8. If questions or clarifications are needed please SMS, skype or call the SCI Programme Advisor Ms Nadia Ben Meriem and/or the MoH National Coordinator Dr Aboulaye Meite.



Treatment in schools involved in monitoring process

Schools selected for monitoring surveys **must** be dealt with in exactly the same way as those not included in the survey. This is to ensure the results represent the whole treatment programme, which will not be true if conditions are different for those groups of people involved in the survey.

- Drug treatments to schools involved in the monitoring survey should be administered <u>at the</u> <u>same time as the national programme</u>
- Drug treatments to schools involved in the monitoring survey should not be given at the time of the survey
- Drug treatments to schools involved in the monitoring survey should be delivered not more than 2 months after survey

No special care or treatment should be given to those schools/communities involved in monitoring surveys. In particular, the following should be **avoided**:

- Extra drug treatments
- Extra training
- Extra education / Information, Education, and Communication messages

A list of any children testing positive should be kept by the school and the district health officers, such that treatment can take place if there is any unexpected delay to the MDA.



Kato Katz SOP

Diagnosis of: Schistosoma mansoni, Trichuris trichiura, Ascaris lumbricoides, Ancylostoma duodenale and Necator americanus

General Principle: people infected with STH or intestinal schistosomes pass the eggs of the worms with their faeces. By examining a stool specimen under a microscope, it is possible to count the number and the type of eggs that are present.

Safety precautions

- The stool should be considered potentially infectious.
- Wear gloves and lab coats whenever handling stool samples.
- Benches, instruments and equipment should be routinely decontaminated with disinfectants after use.
- Materials contaminated with infectious waste should be disinfected before disposal.
- Drinking or eating during laboratory procedures is prohibited.
- Appropriate disinfectant(s) should be used for disposal of contaminated materials, wooden spatulas and specimen containers and for cleaning of workbenches.
- Used specimen containers must be disinfected before washing.

Equipment for Kato Katz

Kato-Katz:

- Stool sample in container (polythene squares tied with grass or plastic pot)
- Microscopic glass slides
- Cellophane sheets (hydrophilic, 30 50µm thick)
- Malachite green (or methylene blue)
- Glycerol
- Metal sieve (Endecott Sieve) with 200 250µm mesh size
- Slide boxes
- Newspapers
- Wooden or plastic applicators
- Forceps
- Kato-Katz plastic template with a hole of 6mm on a 1.5mm thick template (delivering 41.7mg of faeces)

Microscopic examination:

- Microscope
- Hand tally counter
- Laboratory forms

Disinfectants and waste disposal:

- Disinfectant wipes
- Medicated soap



- Methylated spirit
- Waste container (containing disinfectant)

| Preparation of Kato Katz Reagents | Images |
|--|--------|
| Step 1: Weigh out 3g of Malachite green powder (or methylene blue). | |
| Step 2: Dilute it in 100ml of distilled water (this is the "stock solution"). | |
| Step 3: Dilute 60ml of glycerine in 40ml of distilled water*. | |
| Step 4: Take 1 ml of Malachite green (or methylene blue) stock solution and add it to 100ml of the 60% glycerol solution (this is the "working solution"). | |
| Step 5: Cut cellophane into 25mm x 30mm pieces and soak them overnight in the working solution. | |

*In reference books the ratio is 50% or greater glycerol solution (50ml glycerine and 50ml distilled water). In Uganda they have found this makes too light a solution and thus makes it difficult to read slides after some time has passed.

| Kato-Katz Steps | Images |
|---|--------|
| Step 1: Place two glass slides alongside each other and label both slides with the sample number and then place a plastic template on top of each. | |
| Step 2: Place a small amount of the faecal specimen on a newspaper and press through the metal sieve. Using a spatula, scrape the sieved faecal material through the sieve so that only the debris remains on the top. | Fg.3 |
| Step 3: Scrape up some of the sieved faeces from the underside to fill the hole in the templates, avoiding air bubbles and levelling the faeces off to remove any excess. | |
| Step 4: Carefully lift off the templates and place it in a bucket of water mixed with concentrated detergent so that they can be reused. | AL JAL |



| Step 5: Place one piece of the cellophane, which has been soaked overnight in the malachite green (or methylene blue) working solution, over the faecal specimen. | |
|--|----|
| Step 6: Place a clean slide over the top and press it evenly downwards to spread the faeces in a circle (this can be done by inverting the slide onto clean newspaper and pressing firmly). If done well, it should be possible to read newspaper print through the stool smear. | J. |
| Step 7: If hookworm is present in the area, the slide should be read within 60 minutes of processing. After that time, the hookworm eggs disappear. | |
| The ideal time for observing <i>S. mansoni</i> eggs is 24 hours after preparation, however, in bright sunlight the slides clear rapidly and a 24hr delay is not necessary. | |

| Microscopic Examination for S. mansoni and STH | Images |
|--|--------|
| Step 1: After 10 minutes place a little amount of eosin on the slide and place it under microscope using x 10 objective. | |
| Step 2: Count ALL eggs present using a hand tally counter; start in one corner of the sample and systematically scan the whole sample in a 'zig zag' scheme | |
| Step 3: Record the number and the type of each egg on a recording form alongside the sample number. If no eggs are seen, record "0". | |
| Step 4: Each sample should be examined by two technicians, one reading Slide A and the other Slide B | |
| Step 5: 10% of slides A and B should be randomly selected and re-examined by a more experienced technician | |
| Discrepancy in egg count should not be greater than 10% | |
| If discrepancy between readers is greater than 25% all slides should be re-read | |
| Step 6: Once examination of slides is completed, including quality control, remove the faeces and cellophane using a tissue into the waste container. Place all slides used when conducting Kato-Katz into the disinfectant. These slides should be cleaned and used again for the survey. | |



Note: Quality control for Kato Katz slide Reading.

Before Preparation

- Use clean containers for stool collection
- Ensure the re-usable sieves, templates and spatulas are well cleaned and dry
- Clearly and correctly label the stool containers to match the participant ID

During Processing

- When using one large sieve to process many samples, avoid mixing them
- It is advisable to prepare at least two smears per sample to increase on the sensitivity
- Use a different template and spatula for each stool sample
- Ensure the template is placed on a flat surface and the sample flattened on top to achieve the same sample size for each slide
- Ensure the smear is uniformly spread so that newsprint can be read through it on the slide.
- Note that at times the sample may be very watery or mucoid and are forced to do a direct smear, in this case try to estimate the appropriate volume but note it down.

During slide examination

- All slides should be stored properly in slide boxes.
- The slides should be left to clear and examined for hookworm within 30 minutes of preparation but S. *mansoni* can be read 1 hour later but preferably after 24 hours
- Each sample should be examined by two technicians, one reading slide A and the other slide B
- 10% of slides A and B should be randomly selected and re-examined by a more experienced technician
- This can be done internally during each survey or externally after every six months
- The discrepancy in egg count should not be greater than 10%. For example, if reader one scores 50 eggs the other should score at least 45 or at most 55 eggs. When it exceeds 10% the results should be discussed and re-examined together.
- But if the discrepancy between readers is greater than 25% all slides should be re-read.
- In case you want to apply a statistical test, the difference between the reader and quality control person should not be significant



Haemastix SOP

Diagnosis of: Schistosoma haematobium.

All manufactured kits come with instructions on how to use them. It is very important to follow the instructions to ensure the quality of the results.

Equipment for Hemastix test

- Case record form
- Hemastix test strip and Hemastix pot with scale
- Scissors
- Gloves
- Disinfectants and waste disposal



Video demonstration: click on the icon

| Steps for Reagent Strips | Images |
|--|--------|
| Step 1: Collect a fresh urine specimen in a clean plastic container. Ensure that the urine is tested in the field within 2 hours of collection. If there is a delay, refrigerate the specimen if possible. | |
| Step 3: Remove one strip from its bottle (you can cut the strip in two to save resources) and label the strips with the patient identification. | |
| Step 4: Completely immerse the reagent areas of the strip into the urine specimen for a few seconds. | |
| Step 5: When removing the strip, run its edge against the rim of the container to remove any excess urine. | |
| Step 6: Put the strip horizontally on the table so that the chemicals do not mix together. | |



| Step 7: Read the strip between 1 and 2 minutes after it has been | |
|--|--|
| dipped in the urine specimen. | |
| | |
| | |
| Step 8: Match the colour of the strip with the colour chart on the | 211 2111111 SARDIN |
| bottle label and record the results on the monitoring form. Record | |
| "0" if the result is negative. | The second secon |
| | The second se |
| 1= trace non-haemolysed | |
| | |
| 2 = trace haemolysed | |
| | |
| 3 = + | |
| 4 = ++ | |
| | |
| 5 = +++ | |
| | |
| Important Note: | |
| DO NOT LAY THE STRIP ON THE COLOUR CHART AS THIS | |
| WILL SOIL THE CHART | |
| | |
| • It is extremely important to read the strip 1-2mins after it | |
| has been dipped in the urine sample. Any colour changes | |
| that occur after 2 minutes are of no diagnostic value and | |
| should be ignored. | |
| | |
| | |



Urine Filtration SOP

Diagnosis of: Schistosoma haematobium

All manufactured kits come with instructions on how to use them. It is very important to follow the instructions to ensure the quality of the results.

Safety precautions

- The urine should be considered potentially infectious.
- Wear gloves and lab coats whenever handling urine samples.
- Benches, instruments and equipment should be routinely decontaminated with disinfectants after use.
- Materials contaminated with infectious waste should be disinfected before disposal.
- Drinking or eating during laboratory procedures is prohibited.
- Appropriate disinfectant(s) should be used for disposal of contaminated specimen containers and for cleaning of workbenches.
- Used specimen containers must be disinfected before washing

<u>Equipment</u>

General use:

Gloves

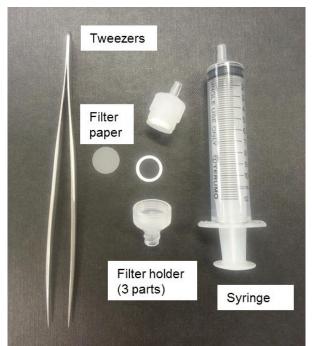
Laboratory Forms

Urine Filtration:

- Urine pots (250ml)
- Swinnex Filter Holder
- Tweezers/Forceps
- Syringe, plastic, 10ml
- Nucleopore Membrane Filter,
- 13mm diameter and pore size $12 \mu m$
 - Microscope glass slides
 - Lugol's Iodine (5% solution)
- Microscopic examination:
 - Microscope
 - Hand tally counter

Disinfectants and waste disposal:

- Bucket (to discard urine)
- 1% hypochlorite solution (domestic bleach)
- Methylated Spirit
- Medicated soap





- Rubber washing gloves
- Disinfectant wipes
- Waste container (containing disinfectant)

Sample collection:

The number of eggs in the urine varies throughout the day, with the highest between 10am and 2pm. The specimen should be taken between these times and consist of a single urine sample. Since eggs are more often found at the end of a urine flow, at least 10ml should be collected at the end of urination (the terminal urine). The easiest way to ensure a terminal urine sample is to ask individuals to 'try to fill' a large pot, e.g. 250ml. Note that some children, particularly those who are heavily infected with schistosomiasis, may not be able to provide 10ml of urine. Do not discard these smaller samples, but note the volume (ml) of urine provided. Specimens should be examined as soon as possible after collection as the eggs may hatch and then become invisible, or crystals may form, making a correct diagnosis more difficult.

IMPORTANT NOTE: To increase the volume of urine provided during sample collection, it would be advisable to promote fluid intake and physical exercise prior to micturition (e.g. provide the children with 2 glasses of water, one hour before urine collection, and request the children to participate in 10 minutes of exercise) (Doehring *et al.* 1983).

| Steps for Urine Filtration | Images |
|--|--------|
| Step 1: Unscrew the filter holder and insert a nucleopore filter between the two parts of the filter holder. Make sure it is correctly held in place before screwing the unit together again. | |
| Step 2: Thoroughly shake and mix the urine specimen before drawing a 10ml specimen into the syringe. Then attach the filter unit. If less than 10ml urine sample is available, withdraw all urine in the sample pot and note the quantity of urine (ml) on the laboratory form next to the ID number. Do not discard the urine sample if it is less than 10ml. | |
| Step 3: Keeping the syringe and the unit in a vertical position, press the plunger down to push all the urine through the filter and out into a bucket. | |



| Step 4: Carefully detach the syringe from the filter unit. Draw air into the syringe, reattach the syringe to the filter unit holder and expel the air again. This is important as it removes any excess urine and ensures that the eggs are firmly attached to the filter. | rest care |
|---|-----------|
| Step 5: Unscrew the filter holder and use a pair of tweezers to remove the filter and place it inverted, onto the glass microscope slide labeled with a unique identification number. The top side of the filter, where the eggs were captured, should be face-up on the slide. | |
| DO NOT DISCARD THE FILTER HOLDER OR SYRINGE. | |
| Step 6: Add one drop of Lugol's iodine and wait 15 seconds for the stain to penetrate the eggs. This makes the eggs more easily visible. | |
| Step 7: Immediately examine the whole filter under a microscope at a low power (x40). Schistosome eggs can be seen clearly because they stain orange. Record the <i>total number of eggs on the</i> <i>filter.</i> | |
| Step 8: At the end of the day, wash all reusable equipment (forceps, filter holders, syringes, urine containers, glass slides) in 1% hypocholorite solution (domestic bleach) for use next day, discard used filters and clean the workbench. | |
| IMPORTANT: Read the slide within an hour of the urine sample bei may be non-viable and become translucent. Do not leave the samp | • •• |

From the slides that have been examined, 10% need to be randomly selected to be checked by a more senior technician. The discrepancy in egg count should not be greater than 10%. For example, if reader one scores 50 eggs the other should score at least 45 or at most 55 eggs. When it exceeds 10% the results should be discussed and re-examined together.



APPENDIX C: Data Collection Forms

Impact Survey - School Information Form

| Date of visit (<i>DD-MM-YYYY</i>) - | - | Re | porters Initials | |
|---|-------------|--------------|------------------|-----|
| A. Site Details | | | | |
| 1. Implementation Unit Name | | | | |
| 2. Implementation Unit Code (DDD) | | | | |
| 3. District | | | | |
| 4. Village | | | | |
| B. GPS (at time of) | | | | |
| 5. Arrival decimal degrees west | <u> </u> | <u> . </u> | | |
| 6. Arrival decimal degrees north | <u> </u> | <u>. . </u> | | |
| 7. Departure decimal degrees west | <u> </u> | <u> . </u> | | |
| 8. Departure decimal degrees north | | . . | | |
| C. School details | | | | |
| 9. School Name | | | | |
| 10. School Code | | | (SSS) | II |
| 11. Name of Headteacher | | | | |
| 12. Contact Number of Headteacher | | | | |
| 13. Have pupils in your school received | 0=No | | | |
| deworming treatment in the last | | 2=PZQ | | |
| year? | - | 4=Don't know | | |
| 14. Lowest Grade taught | 1=CP1 2=CP. | | | |
| | 4=CE2 5=CN | | | II |
| 15. Highest Grade taught | 1=CP1 2=CP | | | 1 1 |
| | 4=CE2 5=CN | 11 6=CM2 | | ۱۱ |

| D. Enrolmen | D. Enrolment numbers | | | | | | | | | |
|-------------|----------------------|----------------|--|--|--|--|--|--|--|--|
| | Boys Enrolled | Girls Enrolled | | | | | | | | |
| Total | 16. | 17. | | | | | | | | |
| CP1 | 18 | 19. | | | | | | | | |
| CP2 | 20 | 21. | | | | | | | | |
| CE1 | 22. | 23. | | | | | | | | |
| CE2 | 24. | 25. | | | | | | | | |
| CM1 | 26. | 27. | | | | | | | | |
| CM2 | 28. | 29. | | | | | | | | |

Mapping and Impact Survey – School WASH Form

| Date of survey (DD-MM-YYYY) | - | Interviewer initials | |
|--------------------------------|------------------------------|-------------------------|--|
| District Name | | District Code | |
| School Name | | School code | |
| *DDD – implementation | unit code, SSS – school code | | |

| A. Observation by Interviewer | | | |
|--|-----|----|---|
| | Yes | No | Observations on |
| School Water | - | • | type/location |
| An improved water source is located on site | | | |
| An improved water source is accessible to all children at school | | | |
| School Hygiene | | | height of station/ease of use |
| A handwashing station with water and soap is present near the latrines | | | |
| A handwashing station with water and soap is present near to kitchen/food preparation area | | | |
| A handwashing station with water and soap is accessible to all children at school | | | |
| School Sanitation | | | Physical structure/cleanliness/access for disability students+staff |
| Latrines are functioning and accessible to all children at school | | | |
| Latrine floors (internal and external) are free from excreta | | | |
| There is ≥1 latrine per 25 girls | | | |
| There is ≥1 latrine per 50 boys | | | |
| There is ≥1 latrine per female teacher/staff | | | |
| There is ≥1 latrine per male teacher/staff | | | |

| B. Answers from Headteacher or Teacher | | |
|--|-----|----|
| | Yes | No |
| School Water | | |
| Do all staff have access to an improved water source at school? | | |
| Do all children have access to an improved water source at school? | | |
| School Hygiene | | |
| Is good hygiene taught at this school? | | |
| School Sanitation | | |
| Did you use a basic sanitation facility last time you defecated at school? | | |



Form 1: School Information Form notes

The School Form is critical for the survey. It will allow background information required for the survey to be gathered. This form must be filled out upon arrival at each of the schools that are participating in the activities of the SCH and STH programme.

Section A: Site Details

Site Details should be filled out on arrival at the location as outlined on the forms.

Date of survey: To be filled on the day of survey following:

Day (DD) – Month (MMM) – Year (YYYY)

Example: (DD-MMM-YYYY): |2|7|-|F|E|B|-|2|0|1|1|

Team Leader Initials: The data collector will record his/her initials in the allocated spot on the form:

Team Leader Initials

Example: John Jones Smith |J|J|S|

1. *Implementation Unit Name*: Record the name of the District here in **BLOCK Capitals** to ensure it is easy to read.

- 2. *Implementation Unit Code*: Fill in the district code (DDD) in accordance with the assigned codes decided pre-survey this should be a 3 digit number: 001 XXX.
- 3. *District*: Record the name here.
- 4. *Village*: Record the name/s here.

Section B: GPS

GPS coordinates must be recorded on site at arrival and departure (stand in the same place for each recording).

Ensure, as per SOP, that the GPS unit is set to decimal degrees format hddd.dddddd

- 5. Arrival decimal degrees west: Record numbers here.
- 6. Arrival decimal degrees north: Record numbers here.
- 7. Departure decimal degrees west: Record numbers here.
- 8. *Departure decimal degrees north*: Record numbers here.

Section C: School Details

School information will be gathered on site through conversations with the Headteacher who will assist you in the survey activities.

- 9. *School Name*: Record the name of the school here in **BLOCK Capitals** to ensure it is easy to read
- 10. *School Code*: Fill in the school code (SSS) in accordance with the assigned codes (see Schools list) this is a 3 digit code: 001– XXX. Schools are numbered (arbitrarily) within each District
- 11. *Name of Headteacher*: Record the name of the Headteacher here in **BLOCK Capitals** to ensure it is easy to read
- 12. Contact Number of Headteacher: mobile number of Headteacher
- 13. *Have pupils in the school received deworming treatment in the last year*?: Write the corresponding number in available space.



0=No 1=ALB 2=PZQ 3=PZQ + ALB 4=Don't know

- 14. *Lowest Class Taught*: Write the corresponding number to the lowest grade taught in the school in the available space.
- 15. *Highest Class Taught*: Write the corresponding number to the highest grade taught in available space

Section D: Enrolment Numbers

Record the enrolment numbers in the available space. The Headteacher will be able to assist you with this section. The total refers to the total school enrolment.

Impact Survey - Individual Registration Form

| School Code (DDD-SSS) (District Code-School Code) | - - | Date of survey (DD-MM-YYYY) | = = = = = = = == |
|--|---------------------|------------------------------------|------------------|
| School Name | | Technician initials | |
| Sex of children registered on page | | Age of children registered on page | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 001 | | | | | | | | | | | | |
| 002 | | | | | | | | | | | | |
| 003 | | | | | | | | | | | | |
| 004 | | | | | | | | | | | | |
| 005 | | | | | | | | | | | | |
| 006 | | | | | | | | | | | | |
| 007 | | | | | | | | | | | | |
| 008 | | | | | | | | | | | | |
| 009 | | | | | | | | | | | | |
| 010 | | | | | | | | | | | | |
| 011 | | | | | | | | | | | | |
| 012 | | | | | | | | | | | | |
| 013 | | | | | | | | | | | | |
| 014 | | | | | | | | | | | | |
| 015 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

² Sewer connections, septic system connections, pour-flush latrines, ventilated improved pit latrines and pit latrines with a slab or covered pit

| School Code (DDD-SSS) (District Code-School Code) | - | Date of survey (DD-MM-YYYY) | = = = |
|--|----------|------------------------------------|---------|
| School Name | | Technician initials | |
| Sex of children registered on page | | Age of children registered on page | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 016 | | | | | | | | | | | | |
| 017 | | | | | | | | | | | | |
| 018 | | | | | | | | | | | | |
| 019 | | | | | | | | | | | | |
| 020 | | | | | | | | | | | | |
| 021 | | | | | | | | | | | | |
| 022 | | | | | | | | | | | | |
| 023 | | | | | | | | | | | | |
| 024 | | | | | | | | | | | | |
| 025 | | | | | | | | | | | | |
| 026 | | | | | | | | | | | | |
| 027 | | | | | | | | | | | | |
| 028 | | | | | | | | | | | | |
| 029 | | | | | | | | | | | | |
| 030 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

| School Code (DDD-SSS) (District Code-School Code) | - | Date of survey (DD-MM-YYYY) | = = = |
|--|----------|------------------------------------|---------|
| School Name | | Technician initials | |
| Sex of children registered on page | | Age of children registered on page | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 031 | | | | | | | | | | | | |
| 032 | | | | | | | | | | | | |
| 033 | | | | | | | | | | | | |
| 034 | | | | | | | | | | | | |
| 035 | | | | | | | | | | | | |
| 036 | | | | | | | | | | | | |
| 037 | | | | | | | | | | | | |
| 038 | | | | | | | | | | | | |
| 039 | | | | | | | | | | | | |
| 040 | | | | | | | | | | | | |
| 041 | | | | | | | | | | | | |
| 042 | | | | | | | | | | | | |
| 043 | | | | | | | | | | | | |
| 044 | | | | | | | | | | | | |
| 045 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

| School Code (DDD-SSS) (District Code-School Code) | - | Date of survey (DD-MM-YYYY) | = = = |
|--|----------|------------------------------------|---------|
| School Name | | Technician initials | |
| Sex of children registered on page | | Age of children registered on page | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 046 | | | | | | | | | | | | |
| 047 | | | | | | | | | | | | |
| 048 | | | | | | | | | | | | |
| 049 | | | | | | | | | | | | |
| 050 | | | | | | | | | | | | |
| 051 | | | | | | | | | | | | |
| 052 | | | | | | | | | | | | |
| 053 | | | | | | | | | | | | |
| 054 | | | | | | | | | | | | |
| 055 | | | | | | | | | | | | |
| 056 | | | | | | | | | | | | |
| 057 | | | | | | | | | | | | |
| 058 | | | | | | | | | | | | |
| 059 | | | | | | | | | | | | |
| 060 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

| School Code (DDD-SSS) (District Code-School Code) | - | Date of survey (DD-MM-YYYY) | = = = |
|--|----------|------------------------------------|---------|
| School Name | | Technician initials | |
| Sex of children registered on page | | Age of children registered on page | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 061 | | | | | | | | | | | | |
| 062 | | | | | | | | | | | | |
| 063 | | | | | | | | | | | | |
| 064 | | | | | | | | | | | | |
| 065 | | | | | | | | | | | | |
| 066 | | | | | | | | | | | | |
| 067 | | | | | | | | | | | | |
| 068 | | | | | | | | | | | | |
| 069 | | | | | | | | | | | | |
| 070 | | | | | | | | | | | | |
| 071 | | | | | | | | | | | | |
| 072 | | | | | | | | | | | | |
| 073 | | | | | | | | | | | | |
| 074 | | | | | | | | | | | | |
| 075 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

| School Code (DDD-SSS) (District Code-School Code) | - | Date of survey (DD-MM-YYYY) | = = = |
|--|----------|------------------------------------|---------|
| School Name | | Technician initials | |
| Sex of children registered on page | | Age of children registered on page | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 076 | | | | | | | | | | | | |
| 077 | | | | | | | | | | | | |
| 078 | | | | | | | | | | | | |
| 079 | | | | | | | | | | | | |
| 080 | | | | | | | | | | | | |
| 081 | | | | | | | | | | | | |
| 082 | | | | | | | | | | | | |
| 083 | | | | | | | | | | | | |
| 084 | | | | | | | | | | | | |
| 085 | | | | | | | | | | | | |
| 086 | | | | | | | | | | | | |
| 087 | | | | | | | | | | | | |
| 088 | | | | | | | | | | | | |
| 089 | | | | | | | | | | | | |
| 090 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

² Sewer connections, septic system connections, pour-flush latrines, ventilated improved pit latrines and pit latrines with a slab or covered pit

41

| School Code (DDD-SSS) (District Code-School Code) | - | Date of survey (DD-MM-YYYY) | = = = |
|--|----------|------------------------------------|---------|
| School Name | | Technician initials | |
| Sex of children registered on page | | Age of children registered on page | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 091 | | | | | | | | | | | | |
| 092 | | | | | | | | | | | | |
| 093 | | | | | | | | | | | | |
| 094 | | | | | | | | | | | | |
| 095 | | | | | | | | | | | | |
| 096 | | | | | | | | | | | | |
| 097 | | | | | | | | | | | | |
| 098 | | | | | | | | | | | | |
| 099 | | | | | | | | | | | | |
| 100 | | | | | | | | | | | | |
| 101 | | | | | | | | | | | | |
| 102 | | | | | | | | | | | | |
| 103 | | | | | | | | | | | | |
| 104 | | | | | | | | | | | | |
| 105 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

| School Code (DDD-SSS) (District Code-School Code) | - - | Date of survey (DD-MM-YYYY) | | |
|--|---------------------|------------------------------------|--|--|
| School Name | | Technician initials | | |
| Sex of children registered on page | | Age of children registered on page | | |

| ID Number | Name | Age | Sex | Class | How long have you lived here? (years) | Do you have access to an improved water source ¹ at school? (Y/N) | Did you use a basic sanitation facility ² last time you defecated at school? (Y/N) | Are you taught about good hygiene in school? (Y/N) | Day 1 stool (tick) | Day 1 urine (tick) | Day 2 stool (tick) | Day 2 urine (tick) |
|--------------|------|-----|-----|-------|--|---|---|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 106 | | | | | | | | | | | | |
| 107 | | | | | | | | | | | | |
| 108 | | | | | | | | | | | | |
| 109 | | | | | | | | | | | | |
| 110 | | | | | | | | | | | | |
| 111 | | | | | | | | | | | | |
| 112 | | | | | | | | | | | | |
| 113 | | | | | | | | | | | | |
| 114 | | | | | | | | | | | | |
| 115 | | | | | | | | | | | | |
| 116 | | | | | | | | | | | | |
| 117 | | | | | | | | | | | | |
| 118 | | | | | | | | | | | | |
| 119 | | | | | | | | | | | | |
| 120 | | | | | | | | | | | | |

¹ Piped water; Public tap or standpipe; Tubewell or borehole; Protected dug well; Protected spring; Rainwater

Impact Survey - Individual Parasitological Form

| School Code (DDD-SSS) (District Code-School Code) | _ _ - | Child Code | |
|--|----------------------|--------------------|--|
| School Name | | (3 digits 001-120) | |

Stool Samples: Kato-Katz

record number of eggs found (do not multiply)

| Date (DD-MM-YYYY) | - - | | - - - | _II |
|-----------------------|---------------|---------------|---------------|---------------|
| Slide | Day 1 Slide A | Day 1 Slide B | Day 2 Slide A | Day 2 Slide B |
| Microscopist initials | | | | |
| S. mansoni | | | | |
| Ascaris | | | | |
| Hookworm | | | | |
| Trichuris | | | | |

Urine Samples: observations, dipsticks and urine filtration

| Date | (DD-MM-YYYY) | - - |
|---|--|----------|
| | Day 1 | |
| Dipstick result (micro-haematuria) | 0 = none 1 = trace non- haemolysed 2 = trace haemolysed 3 = + 4 = ++ 5 = +++ | II |
| Visible Haematuria | 0 = No 1 = Yes | II |
| Volume of urine filtered | (ml) | • |
| Microscopist initials | | |
| <i>S. haematobium</i> Number of eggs | (ensure zero counts are recorded; if missing leave blank) | |



Form 3: Individual Form notes

The completion of this form allows each survey participant to be given a unique identification (ID) number comprised of DDD – district code, SSS – school code and NNN – ID number (00-999). This ID allows the individuals' names to be absent from the Individual Form where the diagnostic results are recorded. This form also collects individual level indicators for WASH.

Please complete the information at the top of the page:

Date of survey: To be filled on the day of survey following:

Day (DD) - Month (MMM) - Year (YYYY)

Example: (DD-MMM-YYYY): |2|7|-|F|E|B|-|2|0|1|1|

Registers Initials: The data collector will record his/her initials in the allocated spot on the form:

|___|__|

Registers Initials

Example: John Jones Smith |J|J|S|

Implementation Unit Name: Record the name of the District here in **BLOCK Capitals** to ensure it is easy to read.

Implementation Unit Code: Fill in the District code (DDD) in accordance with the assigned codes decided pre-survey this should be a 3 digit number: 001 - XXX.

School Name: Record the name of the School here in **BLOCK Capitals** to ensure it is easy to read.

School Code: Fill in the School code (SSS) in accordance with the assigned codes decided presurvey this should be a 3 digit number: 001 – XXX.

A. Individual Details

These questions must be filled in when the individual presents their samples on Day 1.

- Name: Record the first and last names here in **BLOCK Capitals** to ensure it is easy to read
- *Identification Number (DDD.SSS.NNN)*: Insert the district code (DDD): school code (SSS); and individual number (NNN) which should be a 3 digit number: 001 120 which is the sample size.

B. WASH Questions

These questions must be filled in when the individual presents their samples on Day 1.

- Do you have access to an improved water source at school?: Tick one box yes or no
- Did you use a basic sanitation facility last time you defecated at school?: Tick one box yes or no Are you taught about good hygiene in school?: Tick one box yes or no

Form 3: Individual Form

A. Individual

Ask the individual, when they give in their sample, the following questions and record on the form: 1. Sex: Record the gender of the individual using the key on the sheet:

1 = Male; 2 = Female



2. *Grade:* Record the grade of the individual using the key on the sheet:

1 = One; 2 = Two; 3 = Three; 4 = Four; 5 = Five; 6 = Six; 7 = Seven; 8 = Eight

3. *Age*: Record the age of the student in years.

4. *How long have they lived there?* Record the length of time (in years) they have lived in that town.

B: Kato Katz

Samples will be collected on 2 separate days with 2 slides examined from each of the specimen collections.

Date: The date will be recorded on each of the days that the slides are examined. Day 1 and Day

e.g.

| Date (DD-MMM-YYYY) | 2 5 - F E B - 2 0 1 1 | | 2 6 - F E B - 2 0 1 1 | |
|-----------------------|-----------------------|---------------|-----------------------|---------------|
| Slide | Day 1 Slide A | Day 1 Slide B | Day 2 Slide A | Day 2 Slide B |

Microscopist initials: The microscopist who examines slide A and slide B on each of the days must initial in the provided location.

Microscopist Initials Example: John Jones Smith

| | _ | _ _ | |
|-----|----------|-----|--|
| 1 1 | S | | |

| Slide | Day 1 Slide A | Day 1 Slide B | Day 2 Slide A | Day 2 Slide B |
|--------------------------|---------------|---------------|---------------|---------------|
| Microscopist initials | | | | |

Egg count: The egg count for *S. mansoni*, Hookworm, Ascaris and Trichuris needs to be determined and recorded for each slide for each slide.

The number of eggs for each species per slide needs to be recorded.

- Do not multiple this number by 24; ensure that any zeros (0) are recorded and if sample is missing leave blank.
- Where hookworm is not recorded, the record should be scored through or left blank.

| S. mansoni* | | | | |
|-------------|--|------|------|---|
| Hookworm* | | IIII | IIII | |
| Ascaris* | | | | |
| Trichuris* | | IIII | IIII | · |

C Urine Filtration and Dipstick Result

Samples will be collected on 2 separate days with 1 slide and dipstick examined from each of the specimen collections.

Date: Record the date that the Urine filtration and dipstick test are carried out (DD-MMM-YYYY)

E.g. |**2**|**5**|-|**F**|**E**|**B**|-|**2**|**0**|**1**|**1**|



Dipstick result: Record the dipstick result using the key on the box of the dipsticks and corresponding number on the sheet

0 = none; 1 = trace non-haemolysed; 2 = trace haemolysed; 3 = +; 4 = ++; 5 = +++

Visible Haematuria: Record the visible haematuria result i.e. can blood in urine be seen using the key on the sheet.

0 = No; 1 = Yes

Volume of urine: Record the millilitres (ml) of urine collected from the individual. DO NOT THROW OUT URINE IF LESS THAN 10 ml, the volume must still be recorded and sample tested for eggs.

Microscopist initials: The microscopist who examines slide A and slide B on each of the days must initial in the provided location.

Microscopist Initials

|____|___| Example: John Jones Smith |J|J|S|

Egg Count: Count the number of S. haematobium eggs that are found in examination of the filtrated urine

- ALL urine samples but have urine filtration performed on them •
- Ensure that any zero (0) counts are recorded, if the sample is missing leave blank •

Form 4: WASH Form

These questions must be filled in prior to the activity by field team on Day 1.

- Do you have access to an improved water source at school?: Record \checkmark for YES or X for NO
- Are you taught about good hygiene in school?: Record \checkmark for YES or X for NO
- Did you use a basic sanitation facility last time you defecated at school?: Record \checkmark for **YES** or **X** for • NO



Appendix C: Detailed survey methodology & sample size estimation

Deviations from SCI principles in this protocol

This impact study started before SCI survey principles were formalised. The methodology used was based on WHO recommendations applicable at the start of the study (2013).

Sample size details

Per WHO recommendations, 1 site was selected from medium and high prevalence implementation units per every 200,000 SAC. (Per WHO document "Helminth Control in school-age children, A guide for managers of control programmes" (2011)).

Statistical approach to impact surveys

Statistical approach to impact survey methodology & sample size estimation

Scope

These principles are applicable for those programs that are in the 'control of morbidity' phase of a program, and therefore those with reasonable numbers of implementation units classified as being medium or high prevalence. As a program progresses, it is expected that the prevalence and average intensity of schistosomiasis will decrease. In this instance there are two main options available to a program:

- Remain in the 'control of morbidity' phase but at a smaller scale. This could be achieved by decreasing the size of mapping units (e.g. from district to sub-district level). In this instance, the protocol for impact monitoring would be expected to remain unchanged apart from the implementation units used.
- Move to the 'elimination of schistosomiasis' phase. This will most likely involve additional monitoring and new protocols being created. Although SCI is involved in some pilot activities that assess methods of moving towards elimination, we do not believe that this is currently a goal of any of our national programs and any additional protocols will be developed as required.

Implementation units monitored

SCI impact surveys monitor only in those implementation units that were assessed as being moderate or high prevalence during previous mapping exercises. This is for the following reasons:

- The majority of SCI's activities are in mapping units with medium or high prevalence.
- Achieving a reduction in prevalence and intensity in high and moderate implementation units is imperative to control morbidity.
- The cost of monitoring the number of schools required at low prevalence would be prohibitive and outside the WHO guidelines on the proportion of program activities that should be spent on M&E.

Reasons for cross-sectional sampling

We have elected to use cross-sectional sampling (i.e. different children over time) rather than cohort sampling (i.e. the same children over time) in most SCI surveys for the following reasons:

• We believe that cross-sectional sampling is the most appropriate method for measuring SCI program objectives. Cohort studies are most appropriate when assessing the feasibility of MDA programs and measuring changes in morbidity and nutritional markers, but we now believe that there is sufficient evidence of the individual effectiveness of administering PZQ as part of a national program. Therefore, the question that we are now looking to address is the effectiveness of MDA on the school population rather than on individual children. In this instance, cross-sectional sampling is the most appropriate.



- Non-random drop-out from cohort studies (e.g. those most likely to be infected at followup are also those most likely to have dropped out of the study) means that there are statistical issues with analysing cohort data where not all children analysed at baseline have been followed over time. Non-random drop-out can either be for causal reasons such as ill-health or, perhaps more likely, non-causal reasons such as poverty that makes a child both more likely to be infected and to drop out of school. Although there are statistical methods to address drop-out (e.g. mixed models or imputation) we believe that cross-sectional sampling is more robust as it provides a like-for-like comparison of children each year. The assumption of a like-for-like comparison between years requires no external changes between years; however, it should be noted that external changes would likely affect both cohort and cross-sectional sampling equally and therefore there would be no benefit to using cohort sampling above cross-sectional sampling.
 - Prevalence of schistosomiasis is believed to increase with age during primary school. However, cohort sampling means that baseline sampling has to take place in the very youngest children to enable them to be followed over multiple years. The consequence of this is that age-related changes and program changes are confounded over time. The use of cross-sectional sampling enables us to sample the oldest children in the school during each survey, avoiding any issues with confounding.
 - We found in some countries that drop-out was higher than anticipated in cohort studies. For example, in Malawi approximately 40% of children in a cohort study dropped-out between baseline and the first follow-up. If this pattern were to continue over multiple years then there would not be many children in the final survey.

Sample size calculation

SCI sample sizes calculations find the number of schools required in order to have an 80% chance of detecting a 40% reduction in each schistosomiasis species at the national level for SCH. The parameters used in the calculation are:

- True reduction in prevalence assumed to have taken place in the population = 40%. 40% is the minimum target for *S. mansoni* and is less than the ICOSA target for *S. haematobium* of 60%. Therefore this target is somewhat conservative. This is believed to be appropriate as the power calculation itself is relatively low powered at only 80%.
- Initial prevalence in the population: taken from results of mapping only for those implementation units that were assessed as being moderate or high. Initial prevalence is a very important parameter in determining the number of schools required and is calculated on a country-by-country basis.
- Number of children sampled per school = 120. SCI protocol is to sample 120 children per school. This figure was initially determined to allow for anticipated 'drop-out' from cohort studies. Although sample size calculations for cross-sectional studies have indicated that a lower number of children per school may be acceptable, sampling 120 children per schools allows us to examine differences between ages and gender which is important information for program activities. Additionally, 120 children per school enables easy division of division of children into ages and gender, and it is not believed that sampling less children per school would enable more schools to be assessed due to logistical issues of remaining at each school for two days.
- Focal nature of schistosomiasis: Intra-class correlation coefficient = 0.25. Schistosomiasis is often not widespread and occurs in certain areas only, often termed 'hot-spots'. *S. haematobium* is believed to be more focal than *S. mansoni*, and both species are expected to be more focal at low prevalence. How widespread or focal schistosomiasis is can be quantified using the Intra-class Correlation Coefficient (ICC), where a low value indicates widespread disease prevalence and a high value indicates hot-spots. We have used historical data from Zambia and Uganda in order to determine an appropriate ICC of 0.25. SCI plans further research activities to assess ICC across multiple programs and this parameter may change in the future.



- Repeated measures across schools: variable depending on initial prevalence. Sampling the same schools over time leads to a lower number of schools being required compared to sampling different schools over time as the children within a school are expected to be correlated – a school with high prevalence at baseline is expected to have relatively high prevalence at follow-up and vice versa. Additionally, cross-sectional sampling of different children in the same schools is expected to require more schools than cohort sampling of the same children over time as the same children are expected to be more correlated than different children in the same school. Parameterising this correlation is somewhat difficult. The minimum correlation would be if we were to sample in different schools and would be exactly 0. The maximum correlation would be if we were to sample the same children in each school when no children go from negative to positive over time and would vary with initial prevalence. We have assumed that the correlation between children in the same school is exactly in the middle between zero and the maximum correlation. Note that we do not use the WHO suggestion of going to some different schools each year as we are not certain that we have sufficient sample sizes for this to be an appropriate technique. However, we hope to test this strategy in future.
- Alpha = 5%. This is the level at significance will be assessed and is a standard metric.
- **Beta = 80%.** This is the probability of a significant result being obtained given the true reduction in prevalence aimed for. 80% is a standard metric.

Stratification

Once the number of schools to monitor for each schistosomiasis species has been determined, the next step is to stratify the implementation units for co-endemicity. This is to ensure a balance of schools across the different intensity categories of the other schistosomiasis species. Individual schools can be used to monitor for both *S. haematobium* and *S. mansoni* for schools that meet the criteria for both species. The steps taken when stratifying are as follows:

- Create a list of all *S. haematobium* monitoring units i.e. all implementation units that were categorised as medium or high prevalence. Note the total number of *S. haematobium* monitoring units.
- From the above list, create a summary table showing the number of *S*. *haematobium* monitoring units in each *S*. *mansoni* category high, medium and low prevalence.
- Calculate the proportion of S. haematobium monitoring units in each S. mansoni category by dividing the number of S. haematobium monitoring units in each S. mansoni category (step 2) by the total number of S. haematobium monitoring units (step 1).
- Calculate the number of schools to monitor for S. haematobium in each S. mansoni category by multiplying the proportion of S. haematobium monitoring units in each S. mansoni category (step 3) by the total number of schools to monitor for S. haematobium, and rounding to the nearest whole number. Check that the sum of the number of schools to monitor in each category equals the total number of schools to monitor for S. haematobium. If not, then increase or decrease the total number of schools to monitor to adjust for any rounding effects.
- Repeat the above steps for S. mansoni
- Merge the two tables that contain the infection categories for each species and the number of schools to monitor for each species by the infection categories for each species.
- Create a new column showing the total schools to monitor in each category as the maximum of the number of schools to monitor for each species in that category.
- Find the total number of schools to monitor by summing the total schools to monitor in each category.

Site selection

The final step is the selection of specific schools in which to monitor. The SCI biostatistician will be provided with the sampling frame of a list of all schools and associated implementation unit as per



the sampling methodology section above. Sampling is done randomly with no weighting due to school size as sampling proportional to school size may mean that we sample most in urban areas where schistosomiasis prevalence may be less. Additionally, reserve sites are randomly selected from the same implementation unit as the selected site for logistical reasons.

The steps to take for site selection are:

- Remove any schools from the sampling frame that were visited during the mapping exercise. This is because any positive children assessed during mapping should have been treated at the time of assessment.
- Create a subset of the data that includes all of the schools in implementation units that satisfy the first category of the stratification list for *S. haematobium* and *S. mansoni*.
- Randomly select the required number of schools from this infection category.
- Repeat for all infection categories.
- Check that the number of schools selected is equal to the number expected.
- For each implementation unit selected, randomly select two further schools to act as reserve schools for that implementation unit.

Monitoring of STHs

STHs are monitored using the sites selected for schistosomiasis. This is because STH is more widespread than schistosomiasis and therefore the majority of schools selected for schistosomiasis are expected to also have STH infection.

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