PRACTICAL AND PRECISION ASSESSMENTS FOR SCHISTOSOMIASIS

A manual for impact assessments

Version 1

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Acronyms

- IA impact assessment IU – implementation unit
- KK Kato-Katz
- MDA mass drug administration
- PC preventive chemotherapy
- PSU primary sampling unit
- SAC school-aged children
- SCH schistosomiasis
- STH soil-transmitted helminths
- UF urine filtration

Glossary

Impact assessment – a survey conducted after at least 5-6 rounds of effective mass drug administration to determine whether the frequency of treatment should change or remain the same within a unit of implementation.

Implementation unit (IU) - The administrative unit in a country that is used as the basis for making decisions about implementing MDA; typically corresponds to a district.

Practical assessments - district-level (IU) impact assessments designed to determine if the prevalence of schistosomiasis in the district is sufficiently homogenous, such that the same treatment decision would be appropriate for all sub-districts (sub-IUs).

Precision assessments - sub-district-level (sub-IU) impact assessments appropriate in areas where the prevalence is heterogeneous around the 10% threshold and are designed to classify the prevalence in the sub-district as above or below 10%.

Primary sampling unit – the geographic unit that is selected first during sampling; in this manual, the primary sampling unit will be either a school or community.

Purposive sampling – a non-probability sampling technique where the survey planner selects sites to meet a survey goal; in this manual, purposive sampling refers to selecting sites that are expected to have the greatest prevalence of schistosomiasis.

Sub-IU – a smaller administrative area within an implementation unit; typically corresponds to a subdistrict, ward, kebele, aire de santé etc.

Systematic sampling - a probability sampling method in which a random sample, with a fixed periodic interval, is selected from a larger population; in this manual, systematic sampling is used to select sites for the Practical Assessment and to select children in both the Practical and Precision Assessments.

Background

Schistosomiasis (SCH), or bilharzia, is a parasitic disease caused by infection with the trematode bloodflukes schistosomes (Colley *et al.*, 2014). The World Health Assembly resolution 54.19 urges all member states to regularly treat at least 75% of all school-aged children (SAC) who are at risk of morbidity from SCH (WHO 2012). The current control strategy, for the majority of the African Region, recommended by the World Health Organization (WHO) is to first control the morbidity caused by these parasitic infections and then eliminate as a public health problem through preventive chemotherapy (PC) with praziquantel targeting all age groups over two years old (WHO 2011; WHO 2013; WHO 2020). Table 1 shows treatment recommendations for SCH stratified by prevalence category.

Category	Prevalence	Action
High-Moderate Risk	≥10%	Treat all age groups age 2+
Low-risk	<10%	 (i) where there has been a programme of regular PC, to continue the intervention at the same or reduced frequency towards interruption of transmission; or (ii) where there has not been a programme of regular PC, to use a clinical approach of test-and-treat, instead of PC

Table 1. WHO guidelines for treatment of schistosomiasis (WHO 2022)

The majority of SCH-endemic countries throughout sub-Saharan Africa have successfully scaled up preventive chemotherapy with praziquantel through either school or community platforms in districts with moderate and high schistosomiasis infection prevalence. As a result, the epidemiological profile of schistosomiasis infection is expected to have changed considerably and it is important to reassess the prevalence of schistosomiasis post-treatment. The Expanded Special Project for Elimination of NTDs (ESPEN) recommends that SCH programmes that have conducted at least 5 rounds of effective PC (i.e., \geq 75% coverage) conduct impact assessments to determine whether the frequency of treatment should change or remain the same. It is important to point out that in this context, the purpose of an impact assessment is to *classify* the prevalence of SCH in a unit, relative to the target threshold of 10% prevalence; the purpose is not to measure a change in prevalence.

In many settings SCH programmes have historically used administrative or health districts as the unit of implementation. Given the focal nature of SCH transmission, there is now a desire to shift from implementing PC at the district level to a sub-district level, so that treatment is better targeted to only those requiring treatment – thus minimizing over and undertreatment. Consequently, impact assessment surveys need to be able to efficiently and accurately classify endemic sub-districts, while being feasible for SCH programmes to implement. This includes ensuring that planning, implementing, and analysis and interpretation is aligned to existing technical capacity and skills.

To address this programmematic gap, a multi-country study entitled, "The Schistosomiasis Oversampling Study" (SOS) was conducted from 2021-2022. The goal of the SOS was to identify the optimal survey sampling method for conducting impact assessments that is feasible for country programmes, cost-effective and results in accurate treatment classifications of sub-districts. In May of 2023, the SOS study

teams, regional SCH programme managers, international SCH experts, NGO partners, donors, and WHO gathered together in Nairobi, Kenya to review the results of the SOS. The SCH programme managers and experts from the African region reviewed the different survey sampling strategies and ultimately agreed on a single impact assessment strategy, referred to as 'Practical and Precision Assessments" and it was agreed that it be piloted in a number of countries

This manual describes the resulting Practical and Precision Assessments approach, and includes discussion of the underlying concepts, factors to consider when determining what approach is appropriate, and how to interpret the collected data. There is an accompanying protocol template appropriate for submission for ethical review.

Rationale for a two stage approach

Most SCH programmes are transitioning from implementing control interventions for SCH from the IU to sub-IU level to improve targeting and minimize under- and over-treatment. Following conventional methods, this would require a survey in every sub-IU to determine the appropriate treatment strategy for that sub-IU based on observed prevalence. In settings where there are many sub-IU per IU, or many IU, this quickly becomes logistically and financially infeasible. Results from the SOS study and other granular (precision) assessment surveys have highlighted that in many settings, the large majority of communities across entire IUs are either all above, or all below, the decision threshold of 10% prevalence. In such settings, all sub-IUs within the IU should receive the same treatment classification. In other settings where transmission is more focal and there is more variation around the 10% prevalence threshold, different treatment classifications should be assigned to subIUs within the IU. This manual describes a two stage data collection approach that explicitly addresses these different scenarios, whilst ensuring sufficient data can be collected to efficiently classify all sub-IUs to a treatment decision.

Overview of the SPPA methodology

The SCH Practical and Precision Assessment (SPPA) methodology described in this manual serves as a valid approach for conducting programmematic impact assessments for SCH. The Practical and Precision Assessment approach is not considered research; the results generated can be used, by the health ministry leading the assessments, to make decisions about the frequency and geographic area at which to provide SCH treatment. The manual describes *how* to conduct Practical and Precision Assessments, and also includes optional questionnaires designed to assess the feasibility of this approach. This protocol is currently being implemented in several countries across sub-Saharan Africa as a pilot, with the aim of understanding whether the guidance described here is clear, feasible and cost-effective for SCH programmes to implement. Subsequently, following any adaptations based on this pilot, the Practical and Precision Assessment approach and supporting tools will updated and made accessible to all national programmes for conducting impact assessments.

Goal

The goal of the SPPA assessment strategy is to classify sub-IUs (e.g. sub-districts, wards, aire de sante) as being above or below the 10% SCH prevalence threshold, to support ongoing PC treatment decisions

Overview of the approach

Practical and Precision Assessments comprise a two-stage approach to conducting an impact assessment for schistosomiasis. This two-stage approach is designed to accurately and efficiently classify the prevalence of SCH among SAC at the sub-district (sub-IU) level as \geq 10% or <10% to drive appropriate treatment decisions.

A note on terminology: through-out this manual, small SCH implementation units (sub-IUs) are referred to as **sub-districts**. Depending on the setting, these may be wards, sub-districts, aire de sante, or other small administrative units nested within the larger implementation units (IUs) used by other NTD control programmes.

Practical Assessments comprise the first stage of sampling and are conducted at the district (IU) level as a test for heterogeneity. The purpose of Practical Assessments is to determine if the prevalence of SCH within a district is sufficiently similar (or *homogenous*), such that the <u>same</u> treatment decision would be appropriate for all sub-districts within the district. The Practical Assessment is a **15 site x 30 SAC survey**, resulting in a total sample size of **450 SAC per district**.

Precision Assessments are appropriate for making SCH treatment decisions at the sub-district level in districts where the prevalence of SCH is heterogeneous around the 10% threshold. Typically, Precision Assessments would be conducted following a Practical Assessment where the results indicate that SCH is too heterogeneous for the same treatment decision to be applied across all sub-districts. The Precision Assessment is a **4 site** x **20 SAC** survey, resulting in a total sample size of **80 SAC per sub-district**.

It is recommend that these surveys take place at least 6 months after the previous round of preventive chemotherapy.

Determining which assessment type is appropriate

For any given district that is eligible for an impact assessment – at least five rounds of effective (≥75% PC coverage in SAC), an important first step is to determine whether it is appropriate to start with a Practical Assessment at the district-level or proceed directly to a Precision Assessment in each of the sub-districts. The answer to this question needs to be determined by the national programme, based on a careful review of the programmematic data and local knowledge. Table 2 is intended to help capture some of the questions and reasoning that national programmes may wish to use in making this decision.

Table 2 Questions to guide programmes in determining whether to start with a practical assessment or proceed directly to a precision assessment for a given district.

Questions for consideration		Recommended assessment	
Was the prevalence of SCH homogenously high across the district at the time of the last survey (e.g., >50% of sites surveyed had >50% SCH prevalence)?	FYES	Practical Assessment at the district level	
Was the prevalence of SCH generally low across the district at the time of the last survey (e.g., >50% of sites had SCH prevalence close to 10%)?	F YES	Practical Assessment at the district level	
Is the number of sub-districts within the district so great that conducting a Precision Assessment survey within each sub-district would be infeasible and too costly for the programme at this time?	F YES	Practical Assessment at the district level	
Is the historic prevalence data for the district very sparse (<5 sites with prevalence estimates) or non-existent?	F YES	Practical Assessment at the district level	
Do you have any other reason to believe that the prevalence across the district is likely to be homogenous relative to the 10% threshold (e.g., due to universally poor coverage, universally high coverage, or environmental and/or behavioral factors)?	F YES	Practical Assessment at the district level	
Given the historic prevalence data and what is known about programme coverage, is there reason to expect that SCH prevalence is likely to vary around the 10% threshold (e.g., you expect most sites to have prevalence between 0% and 20%)?	F YES	Precision Assessment at the sub-district level	
Is there reason to expect the risk of SCH to vary substantially between sub-districts within the district (e.g., the presence of a snail-infested open waterbody in one of the sub-districts or variation in programme coverage by sub-district)?	FYES	Precision Assessment at the sub-district level	
Did the results of a recent Practical Assessment (or similar district-level impact survey) find between 10% - 50% of sites surveyed had SCH prevalence above the 10% threshold?	F YES	Precision Assessment at the sub-district level	

The next sections describe the sampling methodology for the Practical Assessment and Precision Assessment separately. The reader will note that the Practical Assessment and Precision Assessment utilize the same primary sampling unit, target population and diagnostic tests. Where these two approaches differ is in the survey area (district vs. sub-district) and the methodology for selecting the primary sampling unit, the number of SAC sampled per site, and the interpretation of the results.



Figure 1 Decision tree for the practical assessment and precision assessment approach

Assessment Methodology - Sampling

Sampling for practical assessments

Survey Area

The Practical Assessment should be conducted at the district (IU) level.

Primary Sampling Unit

The preferred primary sampling unit (PSU) is the school; however, implementers may determine that the community is a more appropriate PSU if: (i) school is not in session at the time of the survey, (ii) the programme is worried that low school attendance may bias the results of the survey, or (iii) there is a desire to collect concurrent samples from adults. Either, schools or communities are valid choices for the PSU. For sampling, it is necessary to have sub-district information available for all PSU.

Selecting PSUs for Inclusion

Practical Assessments require sampling in 15 PSUs using systematic sampling. A two-step sampling process is required to select these 15 PSUs. To do this, it is necessary to obtain a list of all the PSUs ordered by sub-district. It is not necessary to include the population of each PSU.

Step 1: Determine the number of PSU per sub-district. The first step is to conduct systematic sampling of sub-districts to ensure that each sub-district has an equal opportunity of selection; it also helps to provide good geographic representation across the district and sub-districts. To aid programmes in determining the number of PSU per sub-district, a simple Excel tool has been built, called the *"Practical Assessment Systematic Sampling Tool"*. Simply enter the total number of sub-districts within a given district and their names and the tool will return the number of PSU that should be selected from each sub-district.

Step 2: Randomly select the PSU. For each sub-district that had \geq 1 PSU selected in Step 1, it is necessary to randomly select this number of PSU. This can be done by numbering each PSU within the sub-district and then randomly drawing a number from the hat. This process should be repeated for all the sub-districts selected in Step 1 until all 15 PSU have been identified.

{NOTE: A tool is being developed to automate this for survey teams}

Target Population

The target population for the Precision Assessments is late school-aged children, ages 10 – 14 years.

Sample size

The Practical Assessment is a 15 site x 30 SAC survey, resulting in a total sample size of 450 SAC per district. This sample size is based on the results of thousands of simulations conducted across archetypes in six different countries and was found to maximize the number of times the district was correctly classified as part of the SOS study https://www.cor-ntd.org/resources/schistosomiasis-oversampling-study-survey-strategy-selection-meeting-report. **Remember:** because the results of a

Practical Assessment are interpreted according to the number of sites with site-level prevalence >10%, standard sample size calculations do not apply.

Selecting Children for Inclusion

The sample size of 30 SAC per PSU represents the number of children targeted who return a valid specimen (urine and/or stool). To account for children who chose not to or cannot provide a sample, we recommend inviting an additional 2 SAC to participate in each PSU. Therefore, in each PSU, 32 SAC (16 girls and 16 boys) should be randomly selected for testing. The following steps can be followed to randomly select 32 SAC from within a primary school.

- 1. Determine the number of girls and boys to sample per class (restrict to classes with children aged 10 to 14 years). Divide 32 by the number of classes in the primary school that are likely to have kids of the target age (10 to 14 years). For example, if there are 6 classes in the school that are likely to have children of the target age, then the number of children to sample from each class is: 32 / 6 = 5.3. Note: round up to the nearest even whole number; in this example, the number of children per class would round up to 6. To ensure gender balance, this would mean 3 girls and 3 boys.
- 2. Assemble all students from these classes. All students within these classes should be separated into class groups and assembled in separate lines one line of boys and one line of girls.

Exclusion criteria: Any child in the selected classes who is outside the target age-group (10-14 years) should not take part in the survey. Similarly, any child who is unwell (e.g. fever) should not take part and should be referred instead to the school health teacher. Any child whose parents have refused their child's participation in the survey should also not be included. All excluded children should be asked to step out of the line.

- 3. **Determine the sampling interval and select the students.** The steps to take for sampling pupils when there are more than boys or girls present than are required for the survey:
 - a. Count the total number of students in the class-and-gender-group line
 - b. For each class-and-gender-group line, calculate the sampling interval (*h*) by dividing the number of children in the line by the number of girls/boys to sample per class (calculated in Step 1). If the resulting sampling interval for that class is a decimal, round down to the nearest whole number. For example, if there are 23 girls in a line for class 4, and we know that 3 girls are needed from each class from Step 1, the sampling interval for girls in that line is 23 / 3 = 7.6, which we then round down to 7. In this case, every 7th girl from this class should be selected.
 - c. Select the first child by randomly selecting a number between 1 and *h*. Random number selection can be done at the school 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. For this example, the sampling interval is 7, so a random number between 1-7 should be chosen. Suppose the randomly selected number is 2. This means the 2nd child in line is the first one to be selected.
 - d. The second child to sample should be the initial number + h. In this case, the second child to sample will be the child that corresponds to the initial number (2) + sampling interval (7) = 9^{th} child in line.

- e. Sampling should then proceed in this manner with every h^{th} child being sampled. The next child to sample will be the 16th child in line (e.g., 9 + 7).
- f. The selected children should be asked to leave the line to provide stool and/or urine samples
- g. If the target sample size for that class-gender is not reached due to some of the selected students being unable or unwilling to provide samples, additional children should be randomly selected until the target number of stool and urine samples for that class-gender has been reached.

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

Sampling for precision assessments

Survey Area

The Precision Assessments should be conducted at the sub-district (sub-IU) level.

Primary Sampling Unit

The preferred primary sampling unit (PSU) is the school; however, the SCH programme may determine that the community is a more appropriate PSU if: (i) school is not in session at the time of the survey, (ii) the programme is worried that low school attendance may bias the results of the survey, or (iii) there is a desire to collect concurrent samples from adults. Either, schools or communities are valid choices for the PSU.

Selecting PSUs for Inclusion

Precision assessments require the purposeful selection of 4 PSUs per sub-district, based on sites that are expected to have the greatest risk of schistosomiasis. **High baseline prevalence, poor programme coverage, proximity to infested water sources, high-risk occupations and migration from high-risk areas may all be used to select the highest-risk PSU**. The SCH programme is encouraged to sit with the district teams to review programme data and discuss local risk factors to make the determination of which PSU to include. In the event that some sub-districts do not have 4 PSUs (e.g., some smaller sub-districts may not have four different primary schools), it is possible to merge two or more sub-districts.

Target Population

The target population for the Precision Assessments is late school age children, ages 10 – 14 years.

Sample size

Precision Assessments require sampling 4 sites x 20 SAC per site, for a total sample size of 80 SAC per sub-district. This sample size is based on the results of thousands of simulations conducted across archetypes in six different countries (https://www.cor-ntd.org/resources/schistosomiasis-oversampling-study-survey-strategy-selection-meeting-report). This sample size results in \pm 6.5% precision for measuring the target threshold of 10%.

Selecting Children for Inclusion

The sample size of 20 SAC per PSU represents the number of children targeted who return a valid specimen (urine and/or stool). To account for children who chose not to or cannot provide a sample, we recommend inviting an additional 2 SAC to participate in each PSU. Therefore, in each PSU, 22 SAC (11 girls and 11 boys) should be randomly selected for testing. The following steps can be followed to randomly select 22 SAC from within a primary school.

- 1. Determine the number of girls and boys to sample per class (restrict to classes with children aged 10 to 14 years). Divide 22 by the number of classes in the primary school that are likely to have kids of the target age (10 to 14 years). For example, if there are 4 classes in the school that are likely to have children of the target age, then the number of children to sample from each class is: 22/4 = 5.5. Note: the answer should be rounded up to the nearest even whole number; in this example, the number of children per class would round up to 6. To ensure gender balance, this would mean 3 girls and 3 boys.
- 2. Assemble all students from these classes. All students within these classes should be separated into class groups and assembled in separate lines one line of boys and one line of girls for each age.

Exclusion criteria: Any child in the selected classes who is outside the target age-group (10-14 years) should not take part in the survey. Similarly, any child who is unwell (e.g. fever) should not take part and should be referred instead to the school health teacher. Any child whose parents have refused their child's participation in the survey should also not be included. All excluded children should be asked to step out of the line.

- 3. **Determine the sampling interval and select the students.** The steps to take for sampling pupils when there are more than the target number (from Step 1) in any class-gender group:
 - a. Count the total number of students in the class-and-gender-group line
 - b. For each class-and-gender-group line, calculate the sampling interval (*h*) by dividing the number of children in the line by the number of girls/boys to sample per class (calculated in Step 1). The answer should be rounded down to the nearest whole number. For example, if there are 17 girls in the Class 2 line, the sampling interval for girls in that line is 17/3 = 5.6 (round down to 5). In this case, every 5th girl from this class should be selected.
 - c. Select the first child by randomly selecting a number between 1 and *h*. Random number selection can be done at the school 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. *In this example, h = 5, so a random number between 1-5 should be chosen. Suppose that random number is 5. This means the 5th child in line is the first to be selected.*
 - d. The second child to sample should be the initial number + *h*. In this example, the next child selected will be spot of the previous child (5^{th}) + sampling interval $(5) = 10^{th}$ child.
 - e. Sampling should then proceed in this manner with every *h*th child being sampled.
 - f. The selected children should be asked to leave the line to provide stool and/or urine samples.

g. If the target sample size for that class-gender is not reached due to some of the selected students being unable or unwilling to provide samples, additional children should be randomly selected until the target number of stool and urine samples for that class-gender has been reached.

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

Assessment Methodology – Survey procedures

Once PSU have been selected, survey procedures are the same for both practical and precision assessments – the only difference being the number of SAC sampled.

All selected PSU (schools or villages) should be informed in advance of the survey team's visit to ensure that the date and time of arrival are conducive to conducting the survey and collecting samples from the children and permission is granted. It is important to pick a time of year when children are most likely to be in school (or when they are most likely to be at home, in the event of a community-based survey).

Upon arrival in a selected PSU, the survey team should introduce themselves to the headmaster of the school (or village chief in the event of a community-based survey) and explain the purpose of the team's visit. The local procedures described for seeking consent should be followed. Once consent from the headmaster or village chief is obtained, the survey team should complete the Site Level form including recording of the site's geographical location using a hand-held global positioning system (GPS) e.g. a smartphone (Appendix 1).

The survey team should then follow the steps outlined in the sampling methodology section "Selecting Children for Inclusion" to randomly select target-age children to enroll in the survey under the supervision of the headteacher or school staff member, such as the health teacher. These children should then be enrolled in the survey using the Participant Form (Appendix 1) and given instructions for providing a urine and/or stool sample on the day of the survey. The samples will be processed that same day on site, or at a nearby location by the survey (parasitological) team.

Laboratory procedures

Every sample collected should be labelled with a unique identification (ID) number (see Data Management section). Stool and urine samples should be examined as per the egg detection and urine dipstick SOPs (Appendices 3 -5) and the intensity of each infection expressed as eggs per slide and eggs per 10ml. To maintain confidentiality, the laboratory technicians will test samples and record results using participant IDs and associated sample numbers.

Survey outcomes

The following outcomes should be measured:

- Schistosoma haematobium: eggs per 10ml of urine using urine filtration method (1 slide)
- Microhaematuria: Number of children with micro haematuria as detected with a reagent dipstick

- Schistosoma mansoni: eggs per gram of faeces using the Kato-Katz method (2 slides, A & B read on day 1)
- **Hookworm** (*Ancylostoma duodenale, Necator americanus*): eggs per gram of faeces using the Kato-Katz method (2 slides, A & B read on day 1)
- Ascaris lumbricoides: eggs per gram of faeces using the Kato-Katz (2 slides, A & B read on day 1)
- **Trichuris trichiura**: eggs per gram of faeces using the Kato-Katz method (2 slides, A & B read on day 1)
- **Demographic composition** (age and sex) of the selected individuals.
- Water contact behaviours of the selected individuals.
- School information

Sample Collection, Diagnostic Tests and Processing

Urine collection

In settings where *S. haematobium* is endemic, all children enrolled should be asked to provide a urine sample. This sample will be tested using urine filtration and urine dipsticks (hemastix). See Appendix 3 and 4 for Standard Operating Procedures (SOP) on urine diagnostic tests.

Stool collection

In settings where *S. mansoni* or soil-transmitted helminths are endemic, stool specimens should be collected for parasitological testing via Kato-Katz. See Appendix 5 for SOP on Kato-Katz.

Sample collection process

1. Each selected student should be asked for verbal consent to provide urine and stool samples (see Appendix 2).

2. Urine samples should be collected between 10am and 2pm.

3. Give the selected students empty urine and stool containers and instruct them how to collect sufficient amounts of urine and stool for testing.

4. When the student has their sample, they should be enrolled at the registration desk and assigned an ID (see Data Management section) their sample pots will each be labelled with the ID and using the same ID, the child's personal details will be collected on the individual form (Appendix 1).

5. A team member or the student submits the samples to the sample processing area where the technicians are processing the urine and stool and reading for eggs.

6. All urine samples should be tested for micro-haematuria first and then 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.

Data Entry & Ancillary Supplies	Waste Disposal
Smartphones/Tablets	Bucket(s) for urine disposal
Chargers	1% hypochlorite solution (domestic bleach)
Backpack to carry supplies	Methylated spirits
Clipboard	Bin bags
Consent forms (if paper-based is required)	Paper towels
Pens and Pencils	Toilet paper
Enrollment/ID sheets	Medicated soap
Notepad	Rubber washing gloves
Calculator	Disinfectant wipes OR tissues and 70% Ethanol
Permanent marker	Waste containers (containing disinfectant)

Recommended Supply List for Lab Teams

(see SOPs for specifications)

General	Urine Filtration
Microscope	Hemastix
Generator (unless lab site has power)	Urine cup with lid
Hand tally counter(s)	Urine filter holder
Permanent marker	10cc syringes
Gloves	Membrane filters
Laboratory coat	Lugol's lodine (5% solution)
Adequate shoes	Kato-Katz
Surgical mask	Kato-Katz kit or individual elements:
Hand sanitizer	Cellophane sheets (hydrophilic, 30 - 50µm thick)
Forceps	Metal sieve
Microscope slides	Wooden or plastic spatulas/ applicators
Slide boxes	Kato-Katz plastic template
Newspaper	Glycerol/dye (Malachite Green or Methylene Blue)
Scissors	Stool container
Data entry form	

Electronic Data Collection via ESPEN Collect

The recommended platform for electronic data collection is ESPEN Collect. ESPEN Collect has the standardized school form, individual enrollment form, and diagnostic results form (see Appendix 1). To initiate support from the ESPEN Collect system, the principal investigator should do the following:

1. Register with ESPEN Collect here: <u>https://espen.afro.who.int/espen-collect-survey-registration</u>

- 2. Submit both the protocol and IRB approval, or an official letter stating that IRB approval is not required, at the time of registration
- 3. The progress of the registration/setup/implementation can be tracked here: <u>https://espen.afro.who.int/tools-resources/espen-collect/registration-summary</u>

Data Management

The ability to correctly link participant enrollment forms with their corresponding lab results (e.g. urine filtration, hemastix and Kato-Katz) is an essential aspect of data management. This requires the careful assigning and use of unique IDs for every individual. To maximize the chances that lab results and participant enrollment forms can be matched at a 1:1 basis, it is recommended that survey teams adhere to the following steps:

- 1. Upon enumerating children and selecting the SAC to participate in the survey, provide each child with a stool (and urine) container and instruct them to go collect a sample.
- 2. When the children return with their sample(s), send them to the enrollment station, where each child will be assigned a unique ID according to the order they appear using DISTRICT CODE _PSU CODE_CHILD NUMBER. For example, suppose the district code is 36 and the PSU code is 002 and this is the first child to arrive with their sample. This child would be assigned the unique ID: 36_002_01. This unique ID should be clearly written on the child's sample containers using permanent marker, and in the paper register.
- 3. Once the unique ID has been assigned, the data recorder should complete the participant form for that child using the ESPEN Collect platform on the smartphone or tablet. The data recorder will need to use double entry to record unique ID for the child to reduce the chances of typing errors. It is a good best practice for the data recorder to check each time to ensure the unique ID they are entering into the device matches what is on the paper register.
- 4. Note: if an error is made when entering data into ESPEN Collect, best practice is to record the error in a paper log sheet (e.g., "for participant 36_002_17 gender was mistakenly entered as 'male' when the correct response should have been 'female'"). At the end of the day this log sheet should be shared (via photo text or email) with the data manager so that the error can be immediately corrected within the database.

After collection, data will be downloaded and automatically transferred via an encrypted connection to a secure ESPEN Collect server if there is a mobile network available in the area. If a mobile network is not available, the data is stored on the phone until it can be transmitted via a Wi-Fi connection to the same secure server. Access to the secure server will be limited to essential personnel within specified user roles. The Data Manager will perform quality control checks daily (or as near to daily as can be achieved) to ensure quality and accuracy of data uploaded to the server.

Data will be stored electronically in the file formats specified above on a secure server. These data belong to the national NTD programme and are intended for making programmematic decisions. It is expected that the NTD programme will share the site-level deidentified data with ESPEN as part of the routine Epi Reporting Form (EPIRF) process.

Common challenges

What to do if a PSU cannot be visited?

If one or more of the selected PSU cannot be visited, a replacement PSU should be randomly selected from the same sub-district. If there are no unsampled PSU in the sub-district that are safe to access, a replacement PSU may be randomly selected from a neighboring sub-district.

What to do if a PSU has less than 30 (practical) / 20 (precision) target-age children?

If the PSU has fewer than the sample size of target-age SAC (10 to 14 years), sampling can stop when all target-age SAC available have been enrolled; there is no need to go to a neighboring site to reach the sample size.

What to do if fewer than 30 (practical) / 20 (precision) target-age children return a urine and/or stool specimen?

One would expect some children not to produce a urine or stool specimen, which is why two additional children are factored into the sampling interval. If the target sample size of children do not produce a viable urine and/or stool sample, the team may select additional children until the target size is reached.

Assessment Methodology – data analysis and interpretation

Analysis and Interpretation for Practical Assessment

For the Practical Assessment, the key unit of analysis is the PSU-prevalence, and not the overall survey mean prevalence. Once all 15 PSU in a district have been visited and the data have been cleaned, the first step in the analysis is to summarize the data **by PSU** (ie school/community). To do this, the Data Manager should calculate the prevalence of SCH within each PSU as follows:

PSU prevalence =	<u># SAC testing positive for SCH in the PSU</u>
	Total # SAC with a valid test result in the PSU

Note that if there are more than one species of SCH present in the district, the results may be combined, such that a child testing positive for <u>either S. haematobium</u> or S. mansoni would be counted as "positive for SCH" and should appear once in both the numerator and denominator. Once the prevalence of SCH has been calculated for each PSU, the PSU results should be entered into the Practical Assessment Results Form (Table 3) and the team should refer to the Decision Tree (Figure 1, recopied below) to identify the appropriate programmematic response.



Table 3 Practical assessment results entry form

District Name	Number of sites with ≥10% SCH	Number of sites with <10% SCH	Programme Decision:
e.g. Murkonna	9	6	Annual preventive chemotherapy to all age groups >2 years of age

Interpretation

Districts with eight or more PSU that have a SCH prevalence ≥10% (RED category): The majority of the sites sampled are above the target threshold for MDA, indicating that SCH is likely to be widespread. Consequently, it is most appropriate to continue to deliver annual MDA to all the sub-districts within the district. Sub-district level assessments are not needed at this time. The programme may want to consider viewing the results on a map to see if any spatial patterns emerge that may help drive specific programme action. For example, if parts of the district have a PSU prevalence that is very high (e.g. >50%), the programme may want to determine whether this is most likely due to high rates of reinfection or poor participation in the MDA.

Districts with no more than one PSU with a prevalence ≥10% (GREEN category): These districts can be considered to have consistently low SCH prevalence and therefore it would be appropriate to consider reducing the frequency of treatment (e.g., decreasing from annual to biennial MDA, or triennial). If one PSU was found to have ≥10% SCH prevalence, the SCH programme may want to deliver targeted annual treatment to that PSU.

Districts with between two and seven communities that have a SCH prevalence ≥10% (YELLOW

category): The national SCH programme is encouraged to critically review the results for districts that fall within this yellow category, as the most appropriate programmematic response may depend on the local situation. The prevalence of SCH in these districts is mixed, meaning that it varies with some sites above 10% and others below, and not enough in either category to make a single treatment decision for the entire district; applying the same treatment decision across all sub-districts may result in over-treating some areas, while under-treating others.

The SCH programme must review the data from the Practical Assessment and decide if:

- a) there is enough information to make a treatment decision in one or more of the sub-districts (e.g., in sub-districts that were sampled at least once during the Practical Assessment, the programme may decide to use the mean prevalence in the sub-district, to make a treatment decision); or,
- b) there is not enough information to make a treatment decision within one or more sub-districts, in which case the programme should proceed to conduct a **Precision Assessment** in each of the indeterminate sub-districts (note: the programme may proceed directly to the Precision Assessments if resources allow; however, the programme may determine that it is preferable to deliver the next round of MDA and conduct the Precision Assessments in the next fiscal year, at least 6 months after the MDA).

When making these determinations, programmes are strongly encouraged to view the PSU results on a map, ideally one that includes the sub-district boundaries. This may help to identify spatial patterns in the distribution of SCH that could help the SCH programme decide whether it is possible to make treatment decisions at the sub-district level without the need for further assessments.

Analysis and Interpretation for Precision Assessments

For Precision Assessments, the key unit of analysis is the sub-district mean prevalence of SCH. Once the data have been collected and cleaned for a given sub-district, the Data Manager should calculate the mean prevalence for the sub-district by combining the data from all 4 PSU sampled within the sub-district as follows:

Mean sub-district prevalence = <u>Total number of children testing positive for SCH across all 4 PSU</u> Total number of children with valid samples across all 4 PSU

Note that if there are more than one species of SCH present in the sub-district, the results may be combined, such that a child testing positive for *either S. haematobium* or *S. mansoni* would be counted as "positive for SCH" and should appear once in both the numerator and denominator. Once the mean prevalence of SCH has been calculated across all PSU for the sub-district, the results should be entered into the Precision Assessment Results Form (Table 4) and the team should refer to the Decision Tree (Figure 1, recopied below) to identify the appropriate programmematic response.

If the mean sub-district prevalence is $\geq 10\%$ (**RED category**) then the recommended programme action is to continue to deliver annual MDA. If the mean sub-district prevalence is <10% (**GREEN category**), then it would be appropriate to consider reducing the frequency of treatment (e.g., decreasing from annual to biennial or triennial MDA).



Table 4 Precision assessment results entry form

Sub-district Name	Mean Prevalence ≥10% SCH	Mean Prevalence <10% SCH	Programme Decision:
e.g. Murkina B	Yes	-	Annual preventive chemotherapy to all age groups >2 years of age

References

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Appendix 1: Survey Forms (for use in ESPEN Collect system)

No. Variable		Label	Entered Value		
1	w_survey_date	Date of survey	Automatically entered		
2	w_recorder_id	Recorder ID	From pre-populated list		
3	w_district	Select the county	From pre-populated list		
4	w_sub-district	Select the sub-district	From pre-populated list		
5	w_school_name	Select the school name	From pre-populated list		
6	w_school_community	Community school is in	Free text field		
6	w_gps	Collect GPS Coordinates	Automatically entered		
7	w_headteacher	Name of head teacher	Free text field		
8	w_headteacher_phone	Contact number of head teacher	Numeric field		
9	w_treatment	How long ago did pupils in your school last receive deworming treatment (PZQ or ALB/MBD or both)?	Never Don't know 1 month 2 - 6 months 6 – 12 months 12-24 moths Over two years ago		
10	w_enrolment	How many children were enrolled at the time of deworming	Numeric field		
11	w_treated	How many children were treated?	Numeric field		
12	w_treated_logiccheck	_treated_logiccheck <i>IF the number (treated/enrolment) is <20% or >100%, check both 10 & 11.</i>			
13	w_remarks				

Site Level (School or Community) Form

Participant Register (paper)

School name: _____

Date:_____

District code: _____ Subdistrict code: _____

#	Name	Sex	Age	Class	Stool (Y/N)	Urine (Y/N)	Notes
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

Participant data	entry form	(electronic)
Participant uata	entry torm	(electronic)

No.	Variable	Label	Entered Value
1	p_survey_date	Date of survey	Automatically entered
2	p_recorder_id	Recorder ID	From pre-populated list
3	p_district	Select the district	From pre-populated list
4	p_subdistrict	Select the sub-district	From pre-populated list
5	p_school_name	Select the school name	From pre-populated list
<mark>6</mark>	p_consent	Did parent or guardian or head teacher consent?	Yes / No
	P_assent	Did the child give assent?	<mark>Yes / No</mark>
7	p_name	Name of pupil	
8	p_participant_ID	Enter participant's ID	Restricted numeric 1-32
9	p_participant_ID2	Re-enter the ID	Restricted numeric 1-32
10	p_age_yrs	Enter the age in years	Restricted numeric 10-14
11	p_sex	Select the sex	Male / Female
12	p_stoolsucces	Was a stool sample successfully collected from this person?	Yes / No
13	p_urinesucces	Was a urine sample successfully collected from this person?	Yes / No
14	p_child_treat	Have you ever been treated with PZQ? (show tablet, or photo of tablet)	Yes/No/Don't remember
15	p_always_lived	Have you always lived here, in this community?	Yes / No
	P_long_lived	<i>If no</i> , when did you move here?	In the last year / more than one year ago / can't remember
16	p_water_play	Did you bathe, swim or play in nearby rivers, streams or ponds in the last week?	Yes/No
17	p_water_fish	Did you go fishing in nearby rivers, streams or ponds in the last week?	Yes/No
18	p_remarks	Additional comment	

Urine tally sheet (paper)

School name: _____

Date:_____

District code: _____ Subdistrict code: _____

#	Dipstick result	mls	Number	Notes
	0 = None	urine	of eggs	
	1 = Trace non-			
	haemolysed			
	2 = Trace			
	haemolysed			
	3 = +			
	4 = ++			
	5 = +++			
1				
2				
2				
3				
5				
4				
5				
6				
7				
8				
-				
9				
10				
11				
11				
12				
13				
14				
15				

		-	
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
L		1	1

Urine Form (electronic)

Question	Variable	Label	Entered Value
1	u_microscopist_id	Microscopist ID	From pre-populated list
2	u_district	Select the district	From pre-populated list
3	u_subdistrict	Select the sub-district	From pre-populated list
4	u_school_name	Select the school name	From pre-populated list
5	U_samples_batch	How many samples were collected in this school?	Restricted numeric 1-32
Open loop s	so that there are respo	nses for n samples	
5	u_participant_ID	Enter participant's ID	Restricted numeric 1-n
6	u_participant_ID2	Re-enter the unique ID	Restricted numeric 1-n
7	u_dipstick	Dipstick result (micro-haematuria)	0 = None 1 = Trace non-haemolysed 2 = Trace haemolysed 3 = + 4 = ++ 5 = +++
8	u_ml_urine	Volume (ml) of urine filtered Do not discard samples less than 10ml	
9	u_sh_egp_ml	Number of eggs recorded	
10	u_remarks	Additional comment	

Kato-Katz Form

Question	Variable	Label	Entered Value			
1	k_microscopist_id	Microscopist ID	From pre-populated list			
2	k_district	Select the district	From pre-populated list			
3	k_subdistrict	Select the sub-district	From pre-populated list			
4	k_school_name	Select the school name	From pre-populated list			
	K_samples_batch	How many samples were collected in this school?	Restricted numeric 1-32			
Open loop	Open loop so that there are responses for n samples					
5	k_participant_ID	Enter participant's ID	Restricted numeric 1-n			
6	k_participant_ID2	Re-enter the ID	Restricted numeric 1-n			
7	k_sch_man_sa	Schistosoma mansoni (eggs) – Slide A				
8	k_sch_man_sb	Schistosoma mansoni (eggs) – Slide B				

9	k_ascaris_lumb_sa	Ascaris lumbricoides (eggs) – Slide A	
10	k_ascaris_lumb_sb	Ascaris lumbricoides (eggs) – Slide B	
11	k_hookworm_sa	Hookworm – Slide A	
12	k_hookworm_sb	Hookworm – Slide B	
13	k_trichuris_sa	Trichuris trichiura – Slide A	
14	k_trichuris_sb	Trichuris trichiura – Slide B	
15	k_other_name_1	Other (name 1)	
16	k_other_quantity_1a	Other Quantity 1 – Slide A	
17	k_other_quantity_1b	Other Quantity 1 – Slide B	
18	k_other_name_2	Other (name 2)	
19	k_remarks	Additional comment	

Appendix 2: Information and Consent Forms

Informed consent process

- 1. The survey team should inform district-level health and education officials of the survey in advance and obtain the contact details of the head teachers of the schools selected for the survey.
- 2. The team should contact the relevant head-teachers to inform them of their involvement in the survey at least one week in advance. Then, head-teachers should be asked to organise an information session with parents the day before the date scheduled for data-collection, or further in advance of the survey day.
- 3. The enumerators' team should arrive at the selected school the day prior to data-collection and do the following:
 - i. Provide the head-teacher with the corresponding information sheet (Form B.1.) and obtain his/her consent to implement the survey (Form B.2.).
 - ii. Provide the head teacher with the information sheet for parents of the selected classes (Forms A.1.).
 - iii. Request a list of enrolled children for each of the classes eligible for the survey.
 - iv. Support the teachers of those classes selected for the survey to explain the activity to children and (Forms A.1).
 - v. Support the meeting with parents to address questions and any concerns.
- 4. Head teachers should provide a copy of the parents' information sheet to the teachers in charge of the classes eligible for the survey. Teachers should read out the forms to the students and hand over a copy. If possible, enumerators should support class teachers to address any questions or doubts.
- 5. At the time of the school meeting with parents, head teachers are expected to explain the survey activities drawing on the information sheets provided by the team. They are also expected to provide copies of the information sheets to the parents present.
- 6. The enumerators' team should try to attain signed consent from the head teacher at the school meeting and use the list of enrolled children for each selected class to keep track of the students with permission to provide samples.
- 7. On the day of data-collection, the survey team should check that children from the selected class have a signed consent form provided by the head teacher. Using the list of children enrolled in each class, they should confirm who has the head teacher's consent form.
- 8. On the day of data-collection, the random selection process for students <u>must only consider those</u> for whom a signed consent form was provided the day before during the school meeting.
- 9. For all those classes, the team should gather assent from them. Attain verbal assent using the corresponding information sheet (C.1.). Ensure that verbal assent is recorded and that two enumerators witness the process.
- 10. The enumerators' team should try to complete the preparations listed above early in the morning of the day of data collection. It is expected they will leave the survey site for the school to be visited by the survey team the next day to repeat the same consent process described above.

Reassessment Survey: Information Sheet – Parents (form A.1)

Measuring prevalence of schistosomiasis and soil transmitted helminths in <country>

Your child is invited to participate in a public health study conducted by the <relevant ministry>. Participating in this activity is entirely up to you. Please take as much time as you need to go over the information sheet. You will be given a copy of this form.

What is the survey about?

'Local term for bilharzia or schistosomiasis' and other 'local term for intestinal worms' are endemic through large parts of <country> and pose a major public health threat. To address this, the <relevant ministry> has conducted mass drug administration activities for schistosomiasis and other worms in recent years. To assess how effective these treatment campaigns have been, we are asking children of both sexes (ages 10-14) to take part in a survey to enable us to estimate how many children in your community remain affected by those parasites.

Why has your child's school been selected to take part?

The school that your child attends was selected from a <relevant ministry> list of schools located in communities at risk for 'local term for bilharzia or schistosomiasis'. A total of xxx have been selected in <country> to ensure we can obtain a representative estimate of the proportion of children in the country who require treatment.

Children of both sexes between 10 to 14 years of age that attend the selected schools are eligible to participate in this study. This selection of participants reflects the population groups targeted by treatment activities, following the guidance of the World Health Organization (WHO).

What will happen if my child takes part in this survey?

On the day of the survey, we will be inviting xx girls and xx boys from your child's school to take part. These children will be selected at random (by lottery) from those children that have consent to take part. If you provide consent, we cannot say in advance whether your child will be selected. *If selected:*

• Your child will be asked to provide one urine sample and one stool sample over the course of a day. Sample pots will be provided to your child at the school at the time of data-collection.

• These samples will be examined by laboratory technicians to identify parasitic material, and their results recorded electronically.

• The enumerators may also ask your child for her/his name, age, sex and some questions on school attendance and sanitation procedures. Each participating class will be called in turns to participate in the study so that any disruption of normal school activities will be kept to a minimum.

• Technicians will examine your child's urine and stool samples in the laboratory using diagnostic tests to detect the presence of worms in the body. If we find that your child is infected with <local term for schistosomiasis>, the Ministry of Health will be informed of the need for treatment activities in this community.

• Your child will be offered treatment for this infection as part of the district wide deworming programme done by the Ministry after the survey has finished.

Are there any risks involved?

We do not anticipate any physical risks for your child's participation. Some children may be embarrassed by the activity or have concerns about their hygiene. To facilitate the process, your child will receive an empty stool and urine containers and instructions about how to safely collect the required urine and stool samples. However, if at any time your child feels uncomfortable with the process, s/he will be free to stop her / his participation. S/he also has the right to avoid answering any questions at any time.

Are there any benefits in my taking part?

Your household is in a community that has been identified as being at risk of contracting 'local term for bilharzia or schistosomiasis'. This study will help to determine how effective treatment activities have been in the area and which treatment strategies may best help to further reduce the presence of 'local term for bilharzia or schistosomiasis' in this region. Reducing the prevalence of the disease in the area is expected to improve children's long-term health.

In case of a positive diagnosis, treatment will be offered as part of the district wide deworming programme done by the <relevant ministry>, once the survey has been completed. Treatment can improve your child's general health status, including less stomach problems/pain while urinating less fatigue and weakness and better nutritional uptake.

Will my children's participation be confidential?

All personal information and diagnostics results will be recorded on electronic forms, which will be kept private. Only a small number of people from the survey team will be allowed to look at information about your child such as their name. After the survey is finished, your child's name will be removed from the data, and the remaining data will be kept in an online data store. No person will be able to link test results to you or your child. The data will be made available to other researchers worldwide for research and to improve medical knowledge. However, your personal information will not be included and there is no way that you can be identified.

What happens if I change my mind?

Your child's participation in the study is voluntary. There are no consequences if you decide s/he should not take part. S/he can stop participation at any time without saying why and refuse answering any questions s/he is not comfortable with.

What happens if something goes wrong?

If you have any questions or concerns about the data collected during the survey, please feel comfortable to stop and talk to us about it.

If at a later stage you may like to withdraw your child's information, or if you later have some concerns about this survey, you may contact us at any time by using the information on the card provided, which includes:

Safeguarding officer: xxxx

<Any other relevant Ministry or Ethics Board Staff for your country>

Reassessment Survey: Information Sheet – Head-Teacher (form B.1)

Measuring prevalence of schistosomiasis and soil transmitted helminths in <country>

Students from the school you direct are invited to participate in a public health study conducted by the <<u>relevant ministry></u>. Please take as much time as you need to go over the information sheet. You will be given a copy of this form.

What is the survey about?

'Local term for bilharzia or schistosomiasis' and other 'local term for intestinal worms' are endemic through large parts of <country> and pose a major public health threat. To address this, the <relevant ministry> has conducted mass drug administration activities for schistosomiasis and other worms in recent years. To assess how effective these treatment campaigns have been, we are asking children of both sexes (10-14) to take part in a survey to enable us to estimate how many children in your community remain affected by those parasites.

Why have your school been selected to take part?

Your school was selected from a <relevant ministry> list of schools located in communities at risk for 'local term for bilharzia or schistosomiasis'. A total of xxx have been selected in <country> to ensure we can obtain a representative estimate of the proportion of children in the country who require treatment.

Children of both sexes between 10 to 14 years of age that attend the selected schools are eligible to participate in this study. This selection of participants reflects the population groups targeted by treatment activities, following the guidance of the World Health Organization (WHO). Children will be selected at random (by lottery) on the day of the survey.

What will happen if my pupils take part in this survey?

- Pupils will be asked to provide one urine sample and one stool sample over a day. Sample pots will be provided to your child at the school at the time of data-collection.
- These samples will be examined by laboratory technicians to identify parasitic material, and their results recorded electronically.
- The enumerators may also ask pupils for he/his name, age, sex and some questions on school attendance and sanitation procedures.
- Each participating class will be called in turns to participate in the study so that any disruption of normal school activities will be kept to the minimum.
- Technicians will examine your child's urine and stool samples in the laboratory using diagnostic tests to detect the presence of worms in the body.
- In the case that pupils are infected with 'local term for schistosomiasis' the Ministry of Health will be informed of the need for treatment activities in this community. Pupils will be offered treatment for this infection as part of the district wide deworming programme done by the Ministry after the survey has finished.

Are there any risks involved?

We do not anticipate any physical risks for your pupils' participation. Some children may be embarrassed by the activity or have concerns about their hygiene. To facilitate the process, pupils will receive an empty stool and urine containers and instructions about how to safely collect the required urine and stool samples. However, if at any time pupils feel uncomfortable with the process, s/he will be free to stop her / his participation. S/he also has the right to avoid answering any questions at any time.

Are there any benefits in my taking part?

Your household is in a community that has been identified as being at risk of contracting 'local term for bilharzia or schistosomiasis'. This study will help to determine how effective treatment activities have been in the area and which treatment strategies may best help to further reduce the presence of 'local term for bilharzia or schistosomiasis' in this region. Reducing the prevalence of the disease in the area is expected to improve children's long-term health.

In case of a positive diagnosis, treatment will be offered as part of the district wide deworming programme done by the <relevant ministry>, once the survey has been completed. Treatment can improve your child's general health status, including less stomach problems/pain while urinating less fatigue and weakness and better nutritional uptake.

Will my pupils' participation be confidential?

All personal information and diagnostics results will be recorded on electronic forms, which will be kept private. Only a small number of people from the survey team will be allowed to look at information about your pupils such as their names. After the survey is finished, your pupils names will be removed from the data, and the remaining data will be kept in an online data store. No person will be able to link test results to your pupils. The data will be made available to other researchers worldwide for research and to improve medical knowledge. However, their personal information will not be included and there is no way that they can be identified.

What happens if I change my mind?

Your pupils' participation in the study is voluntary. There are no consequences if you decide they should not take part. They can also stop their participation at any time without saying why and refuse answering any questions they may not be comfortable with.

What happens if something goes wrong?

If you have any questions or concerns about the data collected during the survey, please feel comfortable to stop and talk to us about it.

If at a later stage you may like to withdraw your students' information, or if you later have some concerns about this survey, you may contact us at any time by using the information on the card provided, which includes:

Safeguarding officer: xxxx

<Any other relevant Ministry or Ethics Board Staff for your country>

Reassessment Survey: Assent form – **Schoolchildren** (form C.1)

We are from the Ministry of Health in <country name>. We are doing a study to learn how many children in your school are affected by [local term for bilharzia] and other [local name for intestinal worms]. This will help us decide how best to stop children from being affected by [local term for bilharzia] in your community.

We are inviting 32 children from your school to take part in this research, and you have been selected by chance. If you don't want to take part, that's okay. If you agree to take part, we will ask you a few very short questions about where you live, and activities you've done in the past week. We will also ask you to provide a stool sample and a urine sample, which we will look at to see if you have any worm infections.

We understand that you might find this a bit embarrassing – we will give you all the material you need to do this, and explain to you how to collect the sample. If we see that you have an infection, you will be offered treatment through school. The information we collect about you might be shared with others, but your name will not be used and will be kept secret. You will not receive anything for taking part in this study.

If you decide to take part, and then change your mind or don't want to carry on, that's OK. We have also asked your parents for permission to take part, and we're only speaking to you about this because they have agreed. Even if your parents say 'yes' you can still decide not to take part. You may ask me any questions about the study. You can call us at any time on the phone number XXXXX.

	yes	no
Do you understand why we are doing the research?		
Are you happy to talk to me?		
Do you understand that you can stop me at any time? And that you don't have to answer questions that you don't want to?		
Are you happy to provide us with a urine sample and a stool sample?		
Are you happy that the information you give may be shared with others?		

Printed name of child

Signature/mark of participant Date

If child cannot read the form themselves, a witness must sign here: I was present while the benefits, risks and procedures were read to the child. All questions were answered and the volunteer has agreed to take part in the research

Printed name of impartial witness
Tick box if participant refuses to have witness present.

I attest that, I have explained the study information accurately in ______ and was understood to the best of my knowledge by the participant and that they have freely given their consent to participate in the presence of the above named impartial witness (where applicable).

Printed name of person obtaining consent

Signature of p. obtaining consent Date

Place

Reassessment Survey: Information Consent Form – Head Teacher (form B.2)

Measuring prevalence of schistosomiasis and soil transmitted helminths in <country>

Place: ______

Date: _____

To show that you understand the information we gave you and that you are happy with your pupils to participate of the survey, we will ask you to confirm that you agree with the following statements by adding your initials to each statement below:

	Person's initials
I have read and understood the information provided about the study and had the opportunity to ask questions to my satisfaction.	
I agree that my pupils take part in this survey and provide the required samples for examination by laboratory technicians.	
I understand that my pupils' real name will not be stored or disclosed to others, that their results will be stored electronically in a secure location, and that after the survey that these results may be shared with other researchers, and that they will not be identifiable from this information.	
I understand that my pupils' participation is voluntary and that they can withdraw at any time without having to provide a reason.	
I confirm that I was provided with alternatives to contact the research team after the survey had taken place to ask further questions, raise concerns or withdraw your participation.	

After confirming you agree with all the statements above, please provide a mark or your signature.

School's name:_____

Headteachers' name: _____

[STAMP THE SIGNED FORM, IF ANY SCHOOL STAMP AVAILABLE]

Appendix 3: Hemastix 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

- Fresh urine sample
- Hemastix test strips
- Scissors
- Colour chart (separate or on test strip container)



Video demonstration: click on the icon haemastix.MPG

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 2: 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 3: Completely immerse the reagent areas of the strip into the urine specimen for a few seconds.	
Step 4: When removing the strip, run its edge against the rim of the container to remove any excess urine.	
Step 5: Put the strip horizontally on the table on top of the urine cup so that the chemicals do not mix together.	
Step 6: Read the strip between 1 and 2 minutes after it has been dipped in the urine specimen.	

Step 7: Match the colour of the strip with the colour chart on the bottle label and record the results in the form. The order of readings on the chart will match the order or results to enter (see below). Record "0" if the result is negative. 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. 	

Appendix 4: 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

Equipment for Urine Filtration:

- Urine pots (250ml), reusable, with fresh urine sample
- Swinnex Filter Holder, reusable
- Tweezers/Forceps, reusable
- Syringe, plastic, 10ml, reusable
- Nucleopore Membrane Filter, 13mm diameter and pore size 12µm 25µm
- Microscope glass slides, reusable
- Lugol's Iodine (5% solution)
- Potentially: cellophane strips, hydrophilic 30-50µm thick, soaked in glycerol



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. If specimens cannot be examined on the same day, keep them in a fridge.

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: Ensure the filter holders and syringes are well cleaned and dry. 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: Mix the urine specimen (shaking or pulling up and down with the syringe) before drawing 10ml of urine into the syringe. Then attach the filter unit (filter holder with filter inside). 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 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.	n on n or n or no
Step 5: Unscrew the filter holder and use a pair of tweezers to remove the filter and place it onto the glass microscope slide labelled 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. Starting in one corner of the sample, systematically scan the WHOLE sample in a 'zig zag' scheme. When moving to a new row, keep a small microscopic field overlap: an object in the corner of the field is chosen and is brought towards the opposite side of the field. Then, the second field is examined. Count ALL eggs on the filter using a hand tally counter. Schistosome eggs can be seen clearly because they stain orange.	
Step 8: Record the total number of eggs on the filter. When no eggs are seen, record "0".	
Step 9: If the slides are kept for QC, cover the stained filter with a glycerol soaked cellophane strip (NO methylene blue or malachite green). Potentially add 4% formalin or SAF-solution for longer storage. If the slides are to be stored, keep them in the fridge to avoid hatching of eggs.	
Step 9: 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 being taken otherwise the eggs may be non-viable and become translucent. Do not leave the samples exposed to the sun. If samples can't be read immediately, store them in the fridge.

Note:

10% of all slides need to be randomly selected and re-examined by a more experienced technician. Results are considered discrepant if egg count differences are:

- For counts below 50 eggs: more than ±5 eggs
- For counts >50 eggs: more than 10% of eggs
- Differing between egg-positive and egg-negative

Discrepant slides are re-read once more by a third technician and final decision on results are made based on all three readings. If more than 50% of QC slides are discrepant on several days, the lead technician should conduct re-training and discuss with the survey team lead about suitable consequences.

Appendix 5: Kato Katz SOP

Diagnosis of: S. mansoni, T. trichiura, A. lumbricoides, and hookworm (A. duodenale and N. 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

- Stool sample in container (polythene squares tied with grass or plastic pot)
- Cellophane sheets (hydrophilic, 30 50µm thick)
- Malachite green (or methylene blue)
- Glycerol
- Metal sieve (Endecott Sieve) with 200 250µm mesh size OR nylon mesh with up to 300 µm mesh size
- Slide boxes
- Microscopic glass slides
- Newspapers
- Wooden or plastic spatulas/ applicators
- Forceps

• Kato-Katz plastic template with a hole of 6mm on a 1.5mm thick template (delivering 41.7mg of faeces), reusable

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 .	Fg.2

*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.	

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. Carefully lift off the templates and place it in a bucket of water mixed with concentrated detergent so that they can be reused.	
Step 4: 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 5: Invert the microscope slide and firmly press the sample against the cellophane strip on another microscope slide or on a smooth hard surface to spread the faeces in a circle. If done well, it should be possible to read newspaper print through the stool smear.	
Step 6: Let the slide clear with the cellophane upwards for 3	0 minutes (less if exposed to sunlight).
If hookworm is present in the area, the slide should be read that time, the hookworm eggs disappear.	within 60 minutes of processing. After

The ideal time for observing *S. mansoni* eggs is within 24 hours after preparation, however, in bright sunlight the slides clear rapidly and a 24hr delay is not necessary.

Images

Step 2: Starting in one corner of the sample, systematically scan the WHOLE sample in a 'zig zag' scheme. When moving to a new row, keep a small microscopic field overlap: an object in the corner of the field is chosen and is brought towards the opposite side of the field. Then, the second field is examined. Count ALL eggs present using a hand tally counter. Make sure not to confuse counters for different species.	
Step 3: Record the sample number and slide on the recording form and note the number and the type of each . If no eggs are seen, record "0".	
Step 4: Remove the faeces and cellophane using a tissue into the waste container and place all slides used when conducting Kato-Katz into the disinfectant. These slides should be cleaned and used again for the survey. Proceed in the same way for the reusable templates and potentially the spatulas.	

Note:

10% of slides (counting both slides A and B) are randomly selected and re-examined by a more experienced technician for quality control (QC). Results are considered discrepant if egg count differences are:

- for counts below 100 eggs: more than ±10 eggs
- for counts >100 eggs: more than ±20% of eggs
- differing between egg-positive and egg-negative

Hookworm eggs will not be considered as they are known to become transparent over time. Discrepant slides are re-read once more by a third technician and final decision on results are made based on all three readings. If more than 50% of QC slides are discrepant on several days, the lead technician should conduct re-training and discuss with the survey team lead about suitable consequences.