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| Liberia: Proposed Cohort Study for Monitoring and Evaluation of the Schistosomiasis and Soil Transmitted Helminth Control Programme |
| Integrated Control of Schistosomiasis and Intestinal Helminths (ICOSA) |

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| ABSTRACT: Schistosomiasis (SCH) is a largely focalized disease and can vary in distribution considerably within a small radius. Globally the disease affects over 200 million and is highly associated with poverty. Soil transmitted helminths (STH) infect over 2 billion people globally, and are transmitted through human contact with warm, moist soil in tropical and sub-tropical resource-poor settings. Through an integrated NTD control programme; SCH and STH can be targeted together using large-scale distribution of praziquantel (PZQ) and albendazole (ALB) in the school health delivery system. To monitor how successful a control programme is, it is essential to measure how effective the preventive chemotherapy is. Prior to implementation, baseline parasitological surveys will be conducted to determine the distribution of disease within schools receiving medication that year. In subsequent years longitudinal follow-up surveys will be used to detect changes in disease intensity levels after treatment. The proposed strategy, in our opinion, is a time efficient and cost-effective protocol; sensitive to budget limitations and potential economical and logistical constraints placed on the ministry. |

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# Background

Data collection for M&E should follow mapping, which is proposed in the four counties of Bong, Lofa, Nimba and Margibi.

To begin the M&E activity, a baseline data collection will be conducted prior to the initiation of large-scale distribution of PZQ within schools to be targeted. Follow up surveys will be conducted annually for the life of the programme to monitor the impact of the health intervention. It will also be necessary to have analysed the mapping data in order to sample only from areas that are categorised as high- or moderate-risk for schistosomiasis.

# Key Assertion

To fully document and report the impact of the control programme for SCH and STH in Liberia, annual surveys following a cohort of individuals for the life of the programme should be conducted.

# Objectives

## General objective

Monitor the large scale distribution of PZQ and ALB and evaluate the impact on health (morbidity), disease intensity and disease transmission (using parasitological indicators for STH and SCH).

## Specific objectives

SO 1. Monitor coverage of drug distribution

* + Indicators (I):
    - I 1.1 Number of school age children (enrolled and non enrolled) who have swallowed the drugs in front of the drug distributor / Number of school age children in the implementation zone
      * Goal: at least 75%
    - I 1.2 Number of school age girls (enrolled and non enrolled) who have swallowed the drugs in front of the drug distributor / Number of school age girls in the implementation zone
      * Goal: at least 75%
    - I 1.3 Number of school age boys (enrolled and non enrolled) who have swallowed the drugs in front of the drug distributor / Number of school age boys in the implementation zone
      * Goal: at least 75%
    - I 1.4 Number of non enrolled school age children who have swallowed the drugs in front of the drug distributor / Number of non enrolled school age children in the implementation zone
      * Goal: at least 75%
    - I 1.5 National coverage: number of districts that are implementing treatment algorithm in a year (annual, biannual or twice in a school cycle) / number of districts endemic for Schistosomiasis
      * Goal: 100%

SO 2. Evaluate the intensity of disease (parasitological indicators for STH and SCH): Measure the change on intensity of infection

* Indicators (I): I 2.1 Target reductions in mean intensity were established at the outset of the ICOSA programme as shown in the table below:

The following will also provide useful measures of success:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Milestone year** | | 2012 | 2014 | 2015 |
| **Number of countries with disease prevalence and**  **intensity reduced from baseline** | | 3 | 6 | 8 |
| **Reduction in intensity in**  **Group 1 & 2 countries from baseline (assuming 75% coverage)** | ***S. mansoni*** | 50-65% | 65-80% | 65-80% |
| ***S. haematobium*** | 65-80% | 75-90% | 75-90% |

* + I 2.2 Percentage of heavily infected children with *S. mansoni*: Number of children with ≥400 eggs per gram in their stool / total number of children tested
  + I 2.3 Percentage of moderate infected children with *S. mansoni*: Number of children with between 100 and 399 eggs per gram in their stool / total number of children tested
  + I 2.4 Percentage of heavily infected children with *S. haematobium*: Number of children with more than ≥50 eggs per 10ml in their urine / total number of children tested
  + Measures of STH intensity will also be evaluated.

SO 3. Evaluate the impact of health indicators: Measure the change in SCH infection-related health indicators

* Indicators (I):
  + I 3.1 Anaemia: Average level of haemoglobin measured in school children after implementation of large-scale distribution of PZQ compared to- average level of haemoglobin detected in school-aged children prior to initiation of the large-scale distribution of PZQ
  + I 3.2 Percentage of children with anaemia: Number of anaemic children (Hb <115g/litre) / Total number of children investigated for haemoglobin status
  + I 3.3 Percentage of children with severe anaemia: Number of children with Hb <70g/litre / Total number of children investigated for haemoglobin status
  + I 3.4 Haematuria: Levels of haematuria detected in school-aged children after implementation of large-scale distribution of PZQ compared to levels of haematuria detected in school-aged children prior to initiation of the large-scale distribution of PZQ
  + I 3.5 Percentage of stunting: Number of children exhibiting stunting/total number of children measured for height and age.
  + I 3.6 Percentage of wasting: Number of children exhibiting wasting/total number of children measured for height, weight and age.

SO 4. Evaluate changes in transmission; additionally this would enable the paramaterization of models to investigate changes in environmental transmission using untreated 6 year olds entering school as a proxy for the wider environmental situation; secondly, it would give further insights into patterns of exposure and infection in such age-groups on a much larger scale than has been achieved to date

* Indicator (I)
  + I 4.1 Prevalence in young children not exposed to treatment (as a proxy for incidence of new cases).
  + I 4.2 Intensity of infection in young children not exposed to treatment
  + I 4.1 Anaemia: Average level of haemoglobin measured in young children not exposed to treatment.
  + I 4.2 Percentage of anaemia in young children not exposed to treatment: Number of anaemic children (Hb <115g/litre) / Total number of children investigated for haemoglobin status.
  + I 4.3 Percentage of young children not exposed to treatment with severe anaemia: Number of children with Hb <70g/litre / Total number of children investigated for haemoglobin status.
  + I 4.4 Haematuria: Levels of haematuria in young children not exposed to treatment.
  + I 4.5 Percentage of stunting in young children not exposed to treatment: Number of children exhibiting stunting/total number of children measured for height and age.
  + I 4.6 Percentage of wasting in young children not exposed to treatment: Number of children exhibiting wasting/total number of children measured for height, weight and age.

# Study Site

# http://www.ezilon.com/maps/images/africa/political-map-of-Liberia.gif

# Materials and Methods

## Study Design

The following outcomes will be measured:

* *S. haematobium*: eggs per 10ml of urine
* *S. mansoni* and soil-transmitted helminths: number of eggs per gram of faeces using the Kato-Katz method (4 slides over 2 days)
* Haematuria:urine dipsticks
* Anaemia:finger prick blood sample and the use of a Hemacue to measure haemoglobin concentration
* Wasting and stunting:height and weight
* Age, how long lived in the area, and sex.

Evaluation will use concurrent longitudinal and cross-sectional studies. The longitudinal study will follow a cohort of randomly sampled primary Grades 1, 2 and 3 (nominally 6, 7 and 8-year-olds) recruited at baseline, carrying out annual measurement. The cross-sectional study will recruit new Grade 1 pupils every year. The aim of the longitudinal study is to monitor prevalence, intensity and morbidity over the course of PCT rounds. The aim of the cross-sectional study is to monitor levels of transmission. If prevalence and intensity decrease over time in the new recruits[[1]](#footnote-2), this could be due to a ‘halo-effect’ of treatment i.e. a reduction in the force of infection.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Year | Age\* in cross sectional study | Age in longitudinal study | | |
| Baseline | 6 | 6 | 7 | 8 |
| Follow-up 1 | 6 | 7 | 8 | 9 |
| Follow-up 2 | 6 | 8 | 9 | 10 |
| Follow-up 3 | 6 | 9 | 10 | 11 |

\*In many countries, the starting age for primary school is fluid so in practice we shall refer to these individuals as in Grade 1.

## Sample Size

Depending on the results of the mapping, we could easily see a situation where both *S. mansoni* and *S. haematobium* are present at sufficient levels so as to justify separate evaluations of each.

To detect a reduction in *S. haematobium* intensity of 65% with 80% power requires an achieved sample of 22 schools, 50 pupils per school. Assuming a 40% follow-up rate within each school over the entire course of the study, this implies a baseline sample of 2,750 pupils i.e. **22 schools, 125 pupils per school**. For details of sample size calculations, please see Appendix C. It is proposed that this baseline sample of 125 per school be split roughly evenly between the three lowest Grades: a minimum of 40 Grade 1; 40 Grade 2 and 40 Grade 3 will total 120 pupils, which is adequate.

To detect a reduction in *S. mansoni* intensity of 50% with 80% power requires an achieved sample of 16 schools, 50 pupils per school. Assuming a 40% follow-up rate within each school over the entire course of the study, this implies a baseline sample of 2,000 pupils i.e. **16 schools, 125 pupils per school**. For details of sample size calculations, please see Appendix C. It is proposed that this baseline sample of 125 per school be split roughly evenly between the three lowest Grades: a minimum of 40 Grade 1; 40 Grade 2 and 40 Grade 3 will total 120 pupils, which is adequate.

For the cross-sectional study, 40 new Grade 1s will be recruited each year.

## Type of schools

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

1. Higher primary school enrolment in Liberia (UNESCO World Data on Education 2010/11) ensures that the majority of children of the desired age group will be included in the sampling frame, minimising selection bias
2. Primary schools present a convenient platform for conducting surveys and delivering treatment to at-risk individuals

## Sampling Methodology

This methodology can be followed for both the *S. haematobium* and *S. mansoni* studies.

The population is the annual and biennial 2012 PCT target population for *S. haematobium/S. mansoni*, which was established from the mapping exercise. High (annual PCT) and moderate-risk (biennial PCT) communities are defined in *Preventive chemotherapy in human helminthiasis* (WHO, 2006). Each district should have been classified into a risk category from the mapping exercise. The sampling frame is the list of schools within this population.

WHO guidelines state that high-risk communities should receive annual treatment and moderate risk communities, biennial treatment. The frequency of treatment will be governed by the highest level of risk from either of the schistosomiasis species.

The method to select primary schools from the sampling frame, is by stratified random sampling. The following is how primary schools should be selected:

* The sampling frame is a list of all primary schools in districts classified as high or medium risk for *S. haematobium/S. mansoni*.
* The sampling frame should be as recent and complete as possible (to avoid bias).
* The sampling frame should be stored in electronic (computerised) format, preferably in a Microsoft Access database or alternatively as a Microsoft Excel spreadsheet.
* If possible, the sampling frame should include:

1. the name of each school\*
2. the village, chiefdom and district\* in which each school is located
3. the identification code of each school
4. the location of each school (geographic co-ordinates)
5. the total number of students in each school
6. whether the school is in a high or medium risk area for *S. haematobium/S. mansoni* \*

\*these are essential elements.

* From the sampling frame for each district, two numbered lists (the two strata) of primary schools should be compiled: one from 1 to *NH*, where *NH* is the total number of primary schools in the high risk districts and one from 1 to *NM*, where *NM* is the total number of primary schools in the medium risk districts.
* *nH* is the number of primary schools in the high risk districts to be sampled and *nM* is the number of primary schools in the medium risk districts to be sampled.

For *S. haematobium*:

*nH* = 22\**NH* /(*NH* + *NM*)

*nM* = 22\**NM* /(*NH* + *NM*)rounded to the nearest whole number.

For *S. mansoni*:

*nH* = 16\**NH* /(*NH* + *NM*)

*nM* = 16\**NM* /(*NH* + *NM*)rounded to the nearest whole number.

* Generate *nH* random numbers between 1 and *NH* and generate *nM* random numbers between 1 and *NM* .This can be done using the =RANDBETWEEN() function in Excel.
* Select primary schools with identification numbers corresponding to the randomly generated numbers for each of the strata. 22 schools should have been selected in total for *S. haematobium*. 16 schools should have been selected in total for *S. mansoni.*

# Study Participant Recruitment

For monitoring and evaluation activities, schools will be contacted as the site of the study. The director of the school will be informed fully about the study and requested to provide informed consent, allowing the study to collect samples from children within the school.

Parents of children at the school will also be informed of the study through school meetings and be requested to provide informed consent for their children to participate within the study. Prior to consent they will be provided with detailed information as to why the study is taking place and questions will be answered by technical staff that are providing the information for the meeting. In addition to this, once children included in the cohort reach age 10, they will also be asked to sign and give informed consent after receiving full information of the study. From those children from which their parents have provided informed consent, random selection will be undertaken by the health workers.

## Frequency of Activities

The baseline survey will be conducted in regions initiating large-scale distribution of PZQ in 2012, prior to the commencement of activities and on the basis of mapping data. In subsequent years, monitoring and evaluation surveys will be conducted just before each future round of PCT. In medium risk areas, where treatment is biennial, surveys will therefore be carried out every other year (in some areas the other schistosomiasis species may increase treatment frequency but monitoring should be as for the specific species being tested). This will yield a mixture of annual and biennial data across the sampled schools for both species for the duration of the programme[[2]](#footnote-3).

# Survey Methods

During the survey, cohorts of 125 children aged 6, 7 and 8 years (i.e. from Grades 1, 2 and 3) will be randomly selected, from each of the 22 (*S. haematobium*)or 16 (*S. mansoni*) schools and enrolled into the study. Kato-katz tests will be used to determine STH and intestinal schistosomiasis. Urinary filtration will be used to determine presence and intensity of infection of urinary schistosomiasis. Furthermore, detection of anaemia and haematuria will also be carried out in children selected to be part of the baseline study. This group of selected children will be followed for the subsequent years and the same indicators measured annually.

WHO approved protocols (Montresor et al. 2002) will be used for this study and the following individual indicators will be used to measure intensity of disease and morbidity:

Faecal examination:

The child will provide a stool (2-3g) and urine (5-30ml) sample for parasitological examination. Stool will be examined by standard Kato-Katz procedures (41.7mg template) for prevalence and infection intensity of *S. mansoni*, hookworm, Trichuris & Ascaris. Since STHs will be measured in both studies, faecal examination will be necessary for both.

Urine examination:

*S.haematobium* infection intensity will be measured by urinary filtration and optical microscopy. Haematuria will be measured using Haemastix. For the *S. mansoni* study, urine examination will not be necessary.

For Growth measure:

Children height and weight will be taken as an indirect measure of nutritional and health status.

Blood sample:

A fingerprick blood sample will be taken for direct measurement of haemoglobin and detection of anaemia (Hb <11.5 g/dl). Using a sterile disposable lancet 10 µL of capillary blood will be collected into a Hemocue cuvette and the haemoglobin level measured. Both cuvette and lancet will be disposed of in a safe manner.

# Data collection and analysis

Paper data collection forms will be used and a double entry system into a bespoke database will be adopted using netbooks procured for this programme. Appendices A and B contain a sample school details form and case record form. Once data has been entered, it should be sent to the SCI biostatistician whereupon it will be analysed for the specific objectives listed above.Materials

[see Mozambique protocol on Sharepoint for example]

# Human Resources

[see Mozambique protocol on Sharepoint for an example]

# Budget

[see Mozambique protocol on Sharepoint for an example]

# Timeframe

[see Mozambique protocol on Sharepoint for an example]

# BASELINE DATA COLLECTION PROTOCOL

### Arriving at the school

The school information form (Appendix A) should be completed by the team leader.

The GPS co-ordinates of the school should be entered. Remember also to re-read and re-enter the coordinates at the end of the visit.

### Selecting the grades

Students should be selected from grades 1 (20 boys and 20 girls), 2 (20 boys and 20 girls) and 3 (20 boys and 20 girls). These are minimum numbers; if a grade contains 45 pupils, for example, it will be more straightforward to sample the entire grade. If there are less than 120 pupils in Grades 1-3 within the sampled school, it will be necessary to top up the sample from a neighbouring school that occupies the same ecological niche.

### Selecting the students

The students should be separated into grades and assembled in lines – one line of boys and one line of girls for each grade to be surveyed

* If more than the required number of students is present in a line[[3]](#footnote-4), they should be selected randomly.
* Calculate the sampling interval (SI) for each grade/gender group (i.e., the number of positions in the line after which a child is selected).
* SI = the total number of students in the line divided by the number of students to be surveyed in that grade/gender group, rounded to the nearest whole number.

*Example There are 105 boys in grade 1 (6 years old), 52 girls in grade 2 (7 years old children) and 22 boys in grade 3 (8 years old children). The SIs are:*

* *Grade 1 105/20 = 5*
* *Grade 2 52/20 = 3*
* *Grade 3 22 is only just above the required number so all boys should be sampled here*
* Select an arbitrary “start” number between 1 and the SI, which corresponds to the position of the first student to be selected.
* Subsequent students are selected by adding SI to the position of the previously selected child (in other words, if SI = 5, every 5th child is selected). Continue to the end of the line. This may result in not enough students being selected (e.g. in the grade 2 example above). If this is the case, top up the sample to the required number by taking students from the very end of the line. In other situations, 20 students will be obtained before reaching the end of the line.

### Collecting the samples

* Each student is asked for consent to provide urine and stool samples.
* Urine samples need to be collected between 10am – 2pm.
* The student is given empty stool and urine containers and is instructed on how to collect sufficient amounts of urine and stool for testing.
* The team leader registers the student, labels the specimens with an identification number and enters the student’s personal details on the Case Record Form (Appendix B).
* The student submits the stool specimen to the “Kato-Katz” table and proceeds to the “urine” table where the urine sample is submitted.

# CLASS OPERATING PROCEDURES

### Safety precautions

* The stool and urine should be considered potentially infectious.
* Wear gloves whenever handling urine and stool samples plus lab coats when 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 cotton wool, wooden spatulas and specimen containers and for cleaning of workbenches.
* Used specimen containers, filter holders and syringes must be disinfected before washing.

### Equipment

* Stool and urine sample collection:
* Gloves, stool and urine containers.
* Urine filtration:
* Gloves, filter holders, filters, syringes, flat forceps.
* Testing for micro-haematuria:
* Gloves, reagent strips (Haemastix).

### Kato-Katz:

Template (41.7mg), cellophane, applicator stick, stool sieving mesh, wooden spatula, Whatman blotting paper, glass slides, methylene blue, eosin, glycerol, tissue paper, insecticide.

### Microscopic examination

Microscope, hand tally counter, Case Record Forms.

Disinfectants and waste disposal:

Chloroxylenol (Dettol), chlorhexidene (JIK), medicated soap, methylated spirits.

Waste container (containing disinfectant).

### Urine filtration

1. Assemble the filter holder by inserting a filter between the two parts of the filter holder.

2. Mix the urine sample thoroughly and draw up 10ml using a syringe.

3. Pass the urine through the filter and remove the syringe from the filter holder.

4. Discard the used syringe in the waste container.

Give the filter holder to the student and instruct him/her to proceed to the microscopy table.

5. Unscrew the lid and remove the filter with flat forceps.

6. Discard the used filter holder in the waste container.

7. Place the filter on a glass slide and quantitatively examine it under the microscope for S haematobium ova.

8. Record the number of eggs on the Case Record Form with the appropriate ID number.

9. Discard the used filter in the waste container.

10. At the end of the day, wash all reusable equipment (forceps, filter holders, syringes, urine containers, glass slides) for use next day, discard used filters and clean the workbench.

### Testing for micro-haematuria

1. Take a reagent strip and cut it into two (lengthwise) with a pair of scissors.
2. Dip one half of the reagent strip into the urine sample for a few seconds. (The other half of the reagent strip will be used for the next student’s specimen).
3. Wait for about 2 minutes and compare the colour of the reagent strip to the colours on the label of the reagent strip container.
4. Write down the result on the Case Record Form with the appropriate ID number.
5. Discard the used reagent strip in the waste container.

### Preparing Kato-Katz reagents

1. Weigh out 0.5g of Methylene Blue powder.
2. Dilute it in 100ml of distilled water (this is the “stock solution”).
3. Dilute 50ml of glycerine in 50ml of distilled water.
4. Take 1 ml of Methylene blue stock solution and add it to 100ml of the 50% glycerine solution (this is the “working solution”).
5. Cut cellophane into 25mm x 30mm pieces and soak them overnight in the working solution.

### Stool processing and Kato-Katz

1. The stool sample is processed immediately while still fresh.

2. Place two glass slides alongside each stool sample.

3. On one end of the slide place a sticker labelled with the ID number from the stool sample container.

4. On the other end of the slide, place a sticker labelled with the date and slide number (1 or 2).

5. Place a template on each of the labelled slides.

6. Take a small portion of stool from the sample container using a wooden spatula.

7. Smear the stool sample on a sieve until sufficient specimen is obtained for processing.

8. Take a small portion of sieved stool with a plastic applicator and transfer it to the slide templates.

9. Remove the templates from the glass slides and discard them in the waste container.

10. Take a piece of prepared cellophane with forceps and place it over each slide’s specimen.

11. Press the slides over blotting paper until there is even spread of the specimen (such that it is transparent) and place the prepared slide into a slide box.

12. Within one hour of preparation, examine the slides quantitatively under the microscope for hookworm eggs. Record the number of eggs on the Case Record Form with the appropriate ID number. If no eggs are seen, record ‘0’.

13. After at least 24 hours, examine the slides quantitatively under the microscope for S mansoni, Ascaris lumbricoides and Trichuris trichiura eggs.

### Microscopic examination for S. mansoni and STH

1. Take a Kato-Katz slide, put a little amount of eosin on the slide and place it under microscope using x 10 objective.

2. Read ALL fields of the slide using the vertical ‘zig zag’ scheme.

3. Count all eggs systemically using hand tally counter.

4. Record the counts on the Case Record Form with the appropriate ID number. If no eggs are seen, record ‘0’.

The same Kato-Katz process requires repetition on the following day yielding four counts for each parasite (see Appendix B).

## 

# GUIDELINES FOR TREATMENT FOR POSITIVE CASES

# Weight dosage charts

Albendazole: 400mg tablet. For treatment of *Ascaris lumbricoides, Trichuris trichiura* and hookworm species infections. Single dose treatment

|  |  |
| --- | --- |
| **Age** | **Dose** |
| Under 1 year | Do not treat |
| 1 – 2 years | ½ tablet |
| Children over 2 years | 1 tablet |
| Adults | 1 tablet |

PZQ: 600mg tablet. For treatment of infection with *Schistosoma mansoni and haematobium.* Single dose treatment. The standard dose is 40mg/kg body weight. Height can also be used to determine dose required according to the WHO PZQ dose pole.

Children under 5 years of age are unlikely to be infected with *S. mansoni and haematobium*, but PZQ is safe for use children aged 1 to 5 years. However no children younger than 6 years old will be included in this study.

|  |  |  |
| --- | --- | --- |
| **Weight (kg)** | **Height (cm)** | **Number of 600mg tablets** |
| 15 – 22.5 | 94 – 110 | 1 |
| 22.5 – 30 | 110 – 125 | 1 ½ |
| 30 – 37.5 | 125 – 138 | 2 |
| 37.5 – 45 | 138 – 150 | 2 ½ |
| 45 – 60 | 150 – 160 | 3 |
| 60 – 75 | 160 - 178 | 4 |
| > 75 | > 178 | 5 |

# Appendix A

## 

# Appendix B



# Appendix C

*S. haematobium*

A dataset from Burkina Faso was used for parameter estimation. Baseline *S. haematobium* prevalence was 54% and mean of the log-transformed egg count was 2.20. The value of *roh*, the intra-cluster correlation, on log-transformed egg counts was 0.25 for the difference between baseline and first follow-up. The correlation between baseline and follow-up log-transformed egg counts was r=0.176. By back-transforming effect sizes for the log-transformed egg-counts, comparisons could be made with the ICOSA targets. For the Burkina Faso data, this back-transformation revealed a reduction in intensity of 96%. From the same starting intensity, to detect a reduction in intensity of 65% with 80% power requires an achieved sample of 22 schools, 50 pupils per school. Assuming a 40% follow-up rate within each school over the entire course of the study, this implies a baseline sample of 2,750 pupils i.e. **22 schools, 125 pupils per school**.

*S. mansoni*

A dataset from the first SCI programme in Uganda was used for parameter estimation. Baseline *S. mansoni* prevalence was 45% and mean of the log-transformed egg count was 2.50. The value of *roh*, the intra-cluster correlation, on log-transformed egg counts was 0.08 for the difference between baseline and first follow-up. The correlation between baseline and follow-up log-transformed egg counts was r=0.558. By back-transforming effect sizes for the log-transformed egg-counts, comparisons could be made with the ICOSA targets. For the Uganda data, this back-transformation revealed a reduction in intensity of 70%. From the same starting intensity, to detect a reduction in intensity of 50% with 80% power requires an achieved sample of 16 schools, 50 pupils per school. Assuming a 40% follow-up rate within each school over the entire course of the study, this implies a baseline sample of 2,000 pupils i.e. **16 schools, 125 pupils per school**. The sample size required for *S. mansoni* monitoring is smaller than that required for *S. haematobium.* The reason for this appears to be the large difference in *roh* on the change scores (0.08 versus 0.25, respectively). *S. haematobium* intensity reductions after PCT are more pronounced and *roh* on the change scores is almost the same as *roh* on the baseline measure (0.29). For *S. mansoni* baseline *roh* is very high (0.45) but is much reduced when looking at difference scores, impacting substantially on required sample size. In epidemiological studies of helminths, the degree of correlation between egg counts in faecal samples from individuals before successful treatment and after a period of further exposure and reinfection is referred to as ‘predisposition’ ([Brooker et al., 2004](#_ENREF_1)). The difference in predisposition between the two species is what is leading to the difference in *roh* and therefore sample size.

Depending on the results of the mapping data, it may be necessary to revise these calculations if starting prevalences are much lower than those observed in the historical datasets.

# References

BROOKER, S., WHAWELL, S., KABATEREINE, N. B., FENWICK, A. & ANDERSON, R. M. 2004. Evaluating the epidemiological impact of national control programmes for helminths. *Trends Parasitol,* 20**,** 537-45.

1. There is a possibility that a newly recruited 6-year-old received treatment the previous year through community-wide distribution. [↑](#footnote-ref-2)
2. Ideally, we would monitor biennial schools every year. In practice, this would mean treating any individuals who were infected every year (for ethical reasons) and would therefore not represent the national picture. It is therefore proposed that they are only surveyed before each round of PCT. [↑](#footnote-ref-3)
3. The pupils per classroom ratio in Malawian primary schools was 104 in 2007 (UNESCO World Data on Education) so it is likely that sampling will be necessary. [↑](#footnote-ref-4)