ICOSA Preventive Chemotherapy (PCT) Coverage survey protocol.

Background

The ICOSA programme provides support to countries developing or scaling up programmes to deliver regular, large-scale schistosomiasis (SCH) and soil-transmitted helminth (STH) treatment for at-risk populations, through repeated rounds of preventative chemotherapy (PCT) using Praziquantel (PZQ) and Albendazole (ALB). One of the key indicators of programme success is programme coverage, that is, the proportion the target population that actually ingested the drug in question. For PZQ, the target population is usually school-age children (SAC), including both school-enrolled and non-enrolled children, and may also include adults at risk of schistosomiasis infection in high prevalence areas. For ALB, the target population is SAC. For ICOSA, the target coverage level is 75% for both drugs, in line with WHO guidelines (WHO, 2011). If high drug coverage is not attained, untreated individuals could potentially act as reservoirs of transmission, hindering control and elimination efforts. Each country collects and submits reported drug coverage, calculated using the number of doses distributed during a round of PCT recorded in treatment registers for the numerator, and population figures (often obtained from census population figures) as the denominator.

To validate the accuracy of reported PCT coverage rates, independent and external drug coverage surveys should be carried out across all areas given PCT, particularly at the beginning of a programme, to ensure that prompt corrective action is taken where sub-optimal coverage is found. In areas where reported coverage is low, additional methods i.e. Key Informant Interviews and Focus Group Discussion are recommended to assess the causes of low coverage (WHO, 2005; WHO, 2010).

The accuracy of reported coverage estimates can be assessed by comparing these with survey-derived coverage estimates and their confidence intervals where reported coverage estimates that lie out of the confidence intervals indicate an over or underestimation of actual coverage. In addition to validation, these coverage surveys also provide a unique opportunity to assess other issues, including knowledge of NTDs and PCT, PCT delivery strategies, biases in treatment coverage for example by age, gender, or ethnicity, and examination of possible reasons for coverage failure. This information assists in the assessment of potential flaws in the PCT delivery system for prompt correction.

Objectives

The specific objectives of this coverage survey are to:

1. Quantify and validate PZQ treatment coverage
2. Assess coverage rates disaggregated by status of school enrolment and gender
3. Collect information on why those eligible did not receive or accept treatment

Survey Design

The aim of this survey is to produce validated coverage estimates of reasonable precision at the implementation unit (IU) level; so that insight can be gained from comparing these with IU-level reported coverage. If possible, it is also desirable for the survey to allow calculation of a single representative validated coverage estimate across all IUs, such that the overall performance of the most recent PCT round can be assessed. For this reason, the survey sample size is designed in order to calculate coverage at the level of individual IUs with reasonable precision. Surveying a number of different IUs from across the implementation area permits an assessment of heterogeneity among IUs in (i) coverage, (ii) the discrepancy between reported and validated coverage and (iii) biases in coverage by gender and school-enrolment. We recommend surveying ~10% of the eligible IUs if possible.

For each country intending to perform a coverage survey, three things must initially be defined:

(i) The implementation unit, which may vary among countries but is often the district or equivalent administrative unit
(ii) The drugs for which coverage needs to be assessed. This is usually PZQ, ALB, or both.
(iii) The target population in which coverage needs to be assessed. This includes individuals that were eligible for treatment in the last round of PCT. This will usually mean all SAC (5-14 year olds) but may include adults in some or all implementation units.

Sampling methods

The coverage survey is household-based, and uses a stratified 2-stage cluster sampling design. In the first stage, all IUs in the implementation area are placed into strata. Strata can be defined in several ways, but should ideally track a variable thought to affect coverage, for example geography (e.g. region or province), the team responsible for treatment delivery or training during PCT, or whether an IU has previously experienced PCT. In order for the survey to produce an unbiased, representative estimate of coverage for the entire implementation area, it is critical that at least one IU be selected in each stratum.

Within each IU selected, the primary sampling units (PSUs) are typically villages, neighbourhoods within cities or enumeration areas (EAs), depending on what kind of sampling frame is available. It is important that this list is mutually exclusive and exhaustive, to ensure that all villages have the opportunity to be selected. The required number of PSUs (henceforth referred to as 'villages' for simplicity) should be selected from the sampling frame with probability proportional to the size of its population (PPS). This necessitates an available sampling frame of villages and their population size (of eligible participants) n for survey design.

Within each selected village, a fixed number of households are selected, and all eligible participants residing at selected households interviewed. Although ideally the survey would include nomadic populations and transient communities, because this is a household-based survey those without a fixed residence will not be included in the survey target population.

As a result of the survey, programme coverage (WHO, 2010) will be estimated as follows:

$$100 \times \frac{\text{Total number of interviewed individuals in the target population that ingested the drug}}{\text{Total number of interviewed individuals in the target population for which drug ingestion could be assessed}}$$

A number of key parameters are used to calculate the size of the survey needed, which are outlined in Box 1.

Country-specific details of survey design (e.g. implementation unit, stratum definition, parameters used in sample size calculations), are given in Annex 1.

Box 1: parameter estimates used in ICOSA coverage survey sample size calculations

- It is assumed that coverage estimates of a pre-specified precision are required at an IU-level (the highest level of resolution) and that sample size calculations need not aim to achieve a pre-specified precision for any particular sub-group (e.g. SAC vs. adults, enrolled vs. non-enrolled children). Thus the precision of coverage estimates for sub-groups will vary according to their frequency in the survey.
- The true coverage is assumed to be **50%**, unless detailed otherwise in Annex 1 on country-specific details. This will give the most conservative (largest) sample size required.
- An intra-class correlation coefficient (*rho*) of 0.1 is assumed. This is based on a review of coverage survey data from several countries: Baker et al. (Baker, et al., 2013), suggested a design effect of 6 is appropriate when designing a district-level NTD PCT coverage survey based on coverage survey results from several countries in sub-Saharan Africa. Assuming approximately 50 individuals were surveyed per district in the reviewed surveys (though this is not explicitly reported in the paper), leads to an estimate of *rho* around 0.1. In countries where IUs are smaller than a district and implementation may therefore be expected to be more homogeneous within an IU, a smaller value of *rho*/design effect may be more realistically assumed during sample size calculations.
- Arguably the biggest driver of cost in coverage surveys is the daily salaries (per diems) for enumerators. Therefore survey design should minimise the time needed for a survey (person-hours), given a pre-specified precision. A cluster size (number of interviews per village) that permits two villages to be surveyed per day rather than just one, is preferable, and will minimise the time needed for the survey. We assume the maximum number of villages that can be surveyed per day is 2, if a relatively small number of participants (e.g. 15-20) are interviewed per village.
- The number of households to be surveyed in each village to achieve this sample size is based on an estimate of the expected number of children per household in the survey region/country. For example, if SAC are the target population and the expected mean number of SAC per household is 3, then the number of households for survey would be 15/3 = 5 to the nearest whole number.
- Non-response rate is assumed to be 20%, leading to a total target number of respondents of 30 per village.
- The average IU population size is considered. Often this will make little difference to the estimated sample size required, though may do when IUs are small.
- A margin of error of 9% percentage points on a 95% confidence interval for the IU coverage estimate was specified as the desired level of precision.

Country-specific sample size

Using these general parameters and country-specific parameters for **Cote d'Ivoire**, sample size calculations (detailed in Annex 1) led to an estimated required sample size of **16 villages per district,** with a sample size of 30 respondents per village. Given an estimated average of 3 eligible participants (SAC) per household, this necessitates visiting ~**10 households per village**, allowing for a small degree of non-response (10-20%). All SAC in the selected households should be interviewed.

Timing of the survey

To minimise recall bias, it is recommended that coverage surveys take place no more than three months after PCT, six months at most (WHO, 2010; Budget *et al*, 2011). The survey should also be timed to ensure that as many of the target population will be at their houses during the survey. Ideally, to target SAC this means timing the coverage survey for the school holidays. This may not always be possible, and a means of interviewing school-attending children from a selected household should be designed. This may involve, for example, taking a list of school-age children identified as household members from the village to the school, and conducting the interviews there.

Sampling procedure

The SCI biostatistician will select the PSUs (e.g. villages) to be surveyed within each IU using *pps* sampling, after being provided with the sampling frame. The sampling frame is a list of all villages/city blocks in the survey area with their associated population sizes. The survey will then be planned to visit the selected villages and interview the required number of households in each. A short list of "reserve villages" will be provided, such that if a selected village cannot be visited for security or other reasons unpredictable until teams are in the field, it can be replaced with another in the same district. Selected should only be replaced with those on the reserve list in extreme circumstances or where it is really impossible to survey that village, and not for reasons of distance, access difficulty and so on. It is important to document in the report any villages that have been replaced and the reason for this replacement, as this might be a reason for low coverage in some areas.

At each selected village, it will be necessary to select the specified number of households to interview. This can take one of two methods, with the first preferable, but the second acceptable when the first is not possible.

Household selection method 1: if a list of all households in the village can be obtained

At village level, the village head or equivalent administrative office would be approached for a list of all households in the village, for example in a village register. A sampling fraction (h) of the households will be calculated:

$$h = \frac{\text{Total number households in village}}{\text{Number of households required}}$$

e.g. if there are 500 houses in the village, and 10 should be interviewed, h=500/10 = 50. If h = 50 then every 50th household in the village register would be selected using systematic sampling, as described below. The first house should be a randomly selected number between 1 and h. Random number selection can be done in the field by writing numbers on pieces of paper, folding them up, placing them in a bowl and mixing before drawing one out at random. Following that, every hth household should then be selected from the household list. For example if the randomly selected number between 1 and 50 was 16, then the 16th house in the village register would be the first house to be sampled and then the 66th house in the village register (16th plus 50 = 66th) and so on until the required number of households is met.

Household selection method 2: If a list of all households is not available

When a list of all households in a village cannot be obtained, the desired number of households will be selected using a modified version of the random walk method (Worrell & Mathieu, 2012; WHO 1991). This is shown in Figure 1 (UNICEF, 1995). In brief, a central location within a village is identified (i.e., a central crossroad near the village leader's home or a village school) where a glass bottle is spun to determine the direction of travel. The survey team will walk along the route most closely aligned with the direction indicated until they reach the village boundary, while simultaneously enumerating all houses along the route. Uninhabited houses, public buildings, or businesses that do not serve as residences should not be included in the enumeration. Once the total number of houses along the route has been counted, a sampling fraction (h) of the households will be calculated:

$$h = \frac{\textbf{Total number households on the random walk}}{\textbf{Number of households required}}$$

For example, if there are 60 houses enumerated on the random walk, and 6 households should be interviewed, the sampling fraction h=60/6 = 10. The first house should be a randomly selected number between 1 and h. Random number selection can be done in the field by writing numbers on pieces of paper, folding them up, placing them in a bowl and mixing before drawing one out at random. This number corresponds to the first household to be interviewed. Following that, every h^{th} household should then be selected from those counted along the route. For example if the number between 1 and 5 was randomly selected to be 4, then the 4^{th} house on the random walk would be the first house to be sampled followed by the 14^{th} house (4^{th} plus the sampling interval (h) of 10) and so on until the required number of households is met.

When to replace a household

If no-one is at home in the selected house, return later in the day. If, again, nobody is at home, indicate this on the survey form in the "Household questions" section, and count this house as one of the houses visited. **DO NOT replace the house with another house**[1].

If people in the selected home refuse to participate, try to encourage participation. If they still refuse, indicate this on the survey form, and count this house as one of the houses visited, indicate this on the survey form. **DO NOT replace the house with another house**.

If there are no eligible individuals for interview in the house (e.g. no SAC live at the address, or all household members moved in after the drug distribution), note this on the survey form, do not ask the questions, but replace the household with the nearest household with any eligible interviewees.

[1] If this happens for many households (e.g. frequently >2 households/village) in several villages, the supervisors should discuss with the study co-ordinator to consider increasing the number of households to randomly select per village.

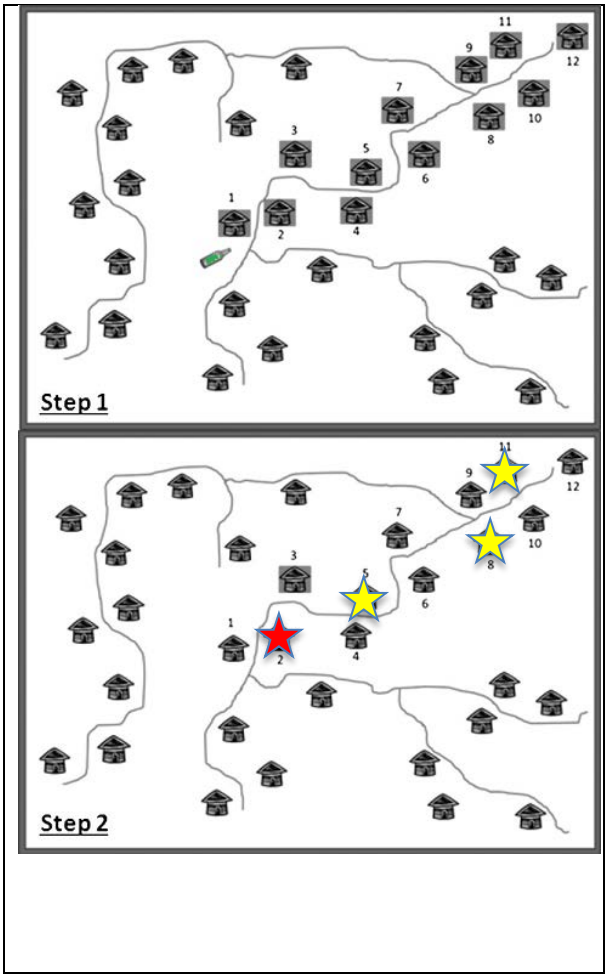

Figure 1: Example of the modified random walk method for selecting households

- If there are 12 houses on the random walk, and 4 households should be interviewed, h=12/4 = 3.
- The first house should then be a randomly selected number between 1 and 3. If, for example, this random number was 2, the 2nd house along the route should be the first interviewed.
- Following that, every 3rd household is selected along the route (since h=3).
- Sampling continues in this manner until a total of four houses have been visited.
- If no household members were present at the time of the initial visit to a selected household, the team returned once to attempt to survey the household before leaving the village. If the house was still empty, the house was marked as absent, but was not replaced.
- They also returned to households where eligible survey participants identified on the first visit were not currently present, to try to interview them later.

Data collection

Data will be collected in two forms: a village form (F1), which summarises data for all villages surveyed in a given district, and a household form (F2), which summarises data for each household where an interview is either performed or attempted. These forms are shown in Annex 2.

Data analysis

Data analysis will be performed by the SCI Biostatistician. This will involve calculation of coverage and confidence intervals using appropriate analytical tools that account for clustering in the data (i.e. interviewees clustered in households and villages). Sub-group analysis (e.g. using multi-level logistic regression) will be used to test how coverage varies according to school enrolment and gender, and across districts.

References

Baker, M.C., *et al.* (2013) Measuring Treatment Coverage for Neglected Tropical Disease Control Programs: Analysis of a Survey Design, *Am J Epidemiol*, **178**, 268-275.
WHO (1991) Training for Mid-Level Managers: The EPI Coverage Survey.
WHO (2005) Monitoring and epidemiological assessment of the programme to eliminate lymphatic filariasis at implementation unit level
WHO (2010) *Monitoring drug coverage for preventative chemotherapy*.
WHO (2011) Helminth control in school-age children: a guide for managers of control programmes.
Worrell, C. and Mathieu, E. (2012) Drug coverage surveys for neglected tropical diseases: 10 years of field experience, *Am J Trop Med Hyg*, **87**, 216-222.

Annex 1: Country-specific details: Cote d'Ivoire

Background on PCT to be assessed

PCT with PZQ and ALB was carried out in 16 districts between the 11th-27th November 2013 (see table below). Four teams from the central level (National Programme) went out to the district to provide training and supervise the treatment. During the first week, the central team trained the nurses and the teachers. In turn, the nurses taught the community health workers, "agents de santé communautaire" (ASC). Furthermore, the central team carried out community radio talk shows as a means of social mobilisation within each district during this time.

The second week was for the administration of the drugs by the teachers and ASC as well as the supervision of the activity by the central team and the nurses. Whilst each nurse was supervising the different schools and villages in their "zone de santé", additional supervision was conducted by the central team. Each team, supervised the PCT administration by randomly selecting several (this number varied by supervisor) villages per day where they supervised how the treatment was given. Each team was composed of five members including two doctors (who led the training), one logistician, one "billeteur" and one driver.

Nombre	**District traité**	**Région**
1	Tiassalé	Agneby Tiassa me
2	Aboisso	Sud-Comoe
3	Adiaké	Sud-Comoe
4	Grand-Bassam	Sud-Comoe
5	Bouaflé	Marahoue
6	Zuenoula	Marahoue
7	Tiebissou	Belier
8	Yamassoukro	Belier
9	Dabakala	Hambol
10	Katiola	Hambol
11	Niakara	Hambol
12	Bouaké Nord-est	Gbéké
13	Bouaké Nord-ouest	Gbéké
14	Sakassou	Gbéké
15	Beoumi	Gbéké
16	Bouaké Sud	Gbéké

Country-specific design aspects for coverage survey

Implementation unit	In Cote d'Ivoire the implementation unit was the district. Thus, in this survey, the district is the uppermost sampling unit.
Stratification	Four teams were responsible for the training and PCT implementation, covering four districts each. Since drug delivery may vary between teams, it was decided that there should be four strata according to the team responsible for PCT, with one district selected per stratum.
Target population	Since schistosomiasis prevalence is low or moderate in all treated districts so far, only SAC were targeted for PZQ PCT. In addition, each SAC received one ALB tablet. While ideally we would design a survey for all SAC, in practice we will only target those living at a permanent residence, i.e. the survey will not capture nomadic or very transient communities as it is household based.
Number of eligible interviewees per household	The average number of target population members (SAC) per household was estimated to be 3
Intraclass correlation coefficient (*rho*) assumed	Our "standard" estimate of *rho*=0.1 was used, as detailed in Box 1.
Survey timing	The survey will take place in school term time, and therefore some school-age children in selected households may be in school at the time of the survey. To capture these individuals, the survey team must find out which school the child in question attends and their name. The school must then be visited to locate these children and interview them away from other children. Every effort must be made to find these individuals, so that the survey adequately captures school-attending children as well as non-enrolled children in an unbiased way. The data collection platform – electronic data forms on mobile phones – will be designed to facilitate this process.
Other sample size parameters	True coverage was assumed to be 50%. District population size was assumed to be 120000 (the largest population size in those districts treated to be conservative), but in practice districts are large enough that variation in population size makes little difference to the estimated sample size required.

Sample size calculation

Assuming *rho*=0.1, true coverage at the district-level is 50%, and a cluster size of 30 SAC (to be interviewed per village) as outlined above, we calculated that to have a 9% margin of error on a 95% confidence interval, **16 villages should be surveyed per district, with 10 households containing SAC interviewed in each village.** This calculation assumed a non-response rate of 10-20%.

Country-specific survey logistics

In Cote d'Ivoire, two teams will be carrying out the coverage survey in four districts namely: Tiassale, Bouake Sud, Niakara and Tiebissou, which were randomly selected from the four strata outlined in the table above, by SCI's biostatistician. Each team will survey two districts as follows:

- In each district, 16 villages will be selected by the SCI biostatistician according to the sampling scheme above.
- Within each village, the team will select a total of 10 households (according to the strategy defined in the sampling procedure above section and interview all eligible participants (SAC).

- Within each team, each surveyor will conduct the interview in two households in each village, and will be responsible for entering the data simultaneously on a paper form for each household interview. It is expected that each team will survey two villages per day.

With regards to training, two full days will be spent in Abidjan at the University of Cocody, where the SCI Programme Manager will train the survey team on the ICOSA coverage survey protocol. Following on from this initial training, harmonisation (practical) training will take place in a few selected villages in one district for a total of three days, as supervised by SCI.

In total there will be two teams. Each team will consist of four people, three interviewers conducting the survey plus a driver.

Two villages will be surveyed per team per day. The first survey will be conducted as early in the morning as possible, when the maximum number of SAC are still at home. Therefore, aim to start the survey in the first village between 6h30 and 7h00. The second village will be sampled in the afternoon.

Timing

Since the survey will be done in school term-time, a method for capturing school-attending children, as well as non-school attending children in an unbiased way is required. This will be achieved in the following way: during the household survey, if a school-age child normally lives in a house but is at school during the enumerator's visit, the name and household head of this child should be noted, and the school later visited to interview the child. Thus at the end of surveying a village, a list will have been made of the names and households of children who need to be interviewed at the local school. Upon arrival at the school, these children should be taken aside from classes, and interviewed in the same way as those in the village. The electronic data forms on the mobile phones will be designed to facilitate this process, and full details are provided in training materials.

Annex 2 FORMS

Form F1: Village Form

District Name		District Code	|___|___|___|
IEP		Interviewers' Initials	|___|___|___|

ICOSA Coverage Survey Form F1 – Village Form

Village details

Village	Village Name	Total population of the village	Total SAC in the village	Number of households in the village	Decimal Degrees East (Arrival & Departure)	Decimal Degrees South (Arrival & Departure)
1.					_____. _____	_____. _____
					_____. _____	_____. _____
2.					_____. _____	_____. _____
					_____. _____	_____. _____
3.					_____. _____	_____. _____
					_____. _____	_____. _____
4.					_____. _____	_____. _____
					_____. _____	_____. _____
5.					_____. _____	_____. _____
					_____. _____	_____. _____
6.					_____. _____	_____. _____
					_____. _____	_____. _____
7.					_____. _____	_____. _____
					_____. _____	_____. _____
8.					_____. _____	_____. _____
					_____. _____	_____. _____
9.					_____. _____	_____. _____
					_____. _____	_____. _____
10.					_____. _____	_____. _____
					_____. _____	_____. _____
11.					_____. _____	_____. _____
					_____. _____	_____. _____
12.					_____. _____	_____. _____
					_____. _____	_____. _____
13.					_____. _____	_____. _____
					_____. _____	_____. _____
14.					_____. _____	_____. _____
					_____. _____	_____. _____
15.					_____. _____	_____. _____
					_____. _____	_____. _____
16.					_____. _____	_____. _____
					_____. _____	_____. _____

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Form F2: Household Form

District Name		Village Name		Interviewer Code	
Date of interview	(DD-MMM-YYYY)	Village Code		Household number	

ICOSA Coverage Survey Form F2 – Household Form

A. Household questions

Was this household interviewed?	Yes, on **first** visit ☐	Yes, on **second** visit ☐	**No** ☐
If household was not interviewed, specify the reason:	Nobody home ☐	Refused to participate ☐	Other ☐ Please specify______________________

B. Individual participant questions

						PRAZIQUANTEL		ALBENDAZOLE				
Member number	Member interviewed? (O/N)	Reason for not participating*	Sex (G/F)	Age	Present during drug distribution (O/N)	Did you swallow PZQ? (O/N)	Reason given if PZQ not taken**	Did you swallow ALB? (O/N)	Reason given if ALB not taken**	Time from home to distribution point***	Where did you take these drugs? ****	How did you hear about the drug distribution? *****
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												

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Response codes for F2: Household Form

Codes for answers to household form questions

	Question	Code to enter for different answers
*	**3:** Reason if not interviewed	**1.** Absent at time of survey **2.** Refused **3.** Unable to answer questions **4.** Other
**	**8** and **10**: Reason given if drug not taken	**1.** Underage **2.** Pregnant **3.** Breast-feeding **4.** Too sick **5.** Working for parents in field **6.** Away from village **7.** Not heard about programme **8.** Drugs finished **9.** Drug distributor did not come **10.** Feels healthy **11.** Medicine does not work **12.** Fear of side-effects **13.** Rumours **14.** Too many tablets **15.** Bad smell / taste / tablets too large **16.** Too old **17.** Other (specify)
***	**11**: Time from home to distribution point	**1.** <30 minutes **2.** 30-60 minutes **3.** 1-2 hours **4.** > 2 hours **5.** Don't know / will not say
****	**12**: Where did you take these drugs?	**1.** School **2.** House or door-to-door **3.** District clinic **4.** Community health post **5.** Other central place in the village (specify) **6.** Other (specify)
*****	**13**: How did you hear about the drug distribution?	**1.** Health worker **2.** Traditional healer **3.** Village chief **4.** Friend/family/neighbour **5.** Village meeting **6.** School meeting **7.** Church / mosque **8.** Radio **9.** TV **10.** Poster **11.** Banner **12.** Leaflet **13.** Don't know **14.** Refuse to answer **15.** Other (specify)