

ADMINISTERING THE TREATMENT COVERAGE URINE SURVEY

1. PURPOSE

This document describes the process by which DeWorm3 study staff will administer the treatment coverage urine survey to eligible participants. The primary assessment of coverage will be by self-report. However, a small number of individuals in each cluster will be approached between 2 and 48 hours after mass drug administration (MDA) and/or National Deworming Day (NDD) and asked to provide a urine sample to be assessed for albendazole metabolites. Results of urine analysis will be used to validate self-reported true coverage of MDA.

2. INTENDED USERS

This document is intended for use by data managers, field managers and field supervisors and any other DeWorm3 staff involved in the administering of the Survey.

3. RESPONSIBILITIES

All relevant DeWorm3 study staff should understand and follow this SOP prior to conducting the Survey. It is the responsibility of the site's Principal Investigator (PI) to ensure that all study staff comply with this SOP during the consenting of study participants who have been deemed eligible on the basis of the Screening/Eligibility criteria and the administration of the Survey.

4. DEFINITIONS

- 4.1. Treatment Coverage Urine Survey:** A survey conducted in a subset of individuals, within the 40 study clusters. Sampled individuals will be asked to provide a urine sample to be assessed for albendazole metabolites during the MDA/post-NDD period. Results of the urine analysis will be used to validate self-reported true coverage.
- 4.2. Treatment Coverage Urine Survey Participant Sample List:** A list of 5 individuals from each of the 40 study clusters who are targeted to provide a urine sample. The sample will be an age-stratified sample 1 preschool-age child (pre-SAC), 1 school-age child (SAC) and 3 adults.
- 4.3. Treatment Coverage Urine Survey Replacement Sampling Lists:** A list of reserve individuals from each cluster who may be approached for inclusion in the Urine Sample Coverage Survey in the event that individuals from the Urine Sample Coverage Survey Participant Sample List are unavailable, ineligible or unwilling to participate.
- 4.4. Exclusion criteria** are conditions which prevent participation in the Treatment Coverage Urine Survey. Exclusion criteria include: individuals who refuse consent/assent, is unavailable to provide a urine sample within the 48 hour post-treatment period or is unable to provide a urine sample within one hour of the study staff visiting.

5. REQUIRED MATERIALS

- 5.1.** Smartphone preloaded with SurveyCTO Treatment Coverage Urine Survey
- 5.2.** Study Information Sheets, in local language
- 5.3.** Treatment Coverage Urine Survey Participant sample list
- 5.4.** Treatment Coverage Urine Survey consent form in local language
- 5.5.** Treatment Coverage Urine Survey assent form in local language
- 5.6.** Clipboard and black pen
- 5.7.** Ink pad, and wiping cloth
- 5.8.** Binder or folder for filing all completed consent and assent forms
- 5.9.** One barcode per individual
- 5.10.** Coloured permanent marker pens

- 5.11. Urine Collection Kits: 50ml containers (50ml polypropylene tubes with screwcap - Item #6255 – Globe Scientific Inc), tissue, bag
- 5.12. Latex gloves
- 5.13. 10ml tubes (10ml polypropylene transport tubes with screwcap Item #6102 – Globe Scientific Inc) for aliquoting
- 5.14. Freezerworks labels

6. PROCEDURE

6.1. Procedure overview

- a) Administration of the Treatment Coverage Urine Survey will take place during the NDD and MDA period.
- b) All individuals will be treated through the normal channels (by teachers during NDD or by community drug distributors (CDDs) and field workers during the community-wide MDA).
- c) Individuals less than 24 months of age will not be sampled
- d) Sharing of the sample lists with study sites and subsequent data collection activities will take place in three ways:
 - i. For all pre-SAC and SAC individuals sample lists will be shared with site teams on the day of NDD with data collection activities beginning the following day. Site teams will have 48 hours in which to deliver the coverage survey and collect urine samples from sampled individuals from 10am on NDD.
 - ii. For adults in control clusters sample lists will be shared on NDD with data collection taking place spread out over the course of the MDA period.
 - iii. For adults in intervention clusters the sample lists will not be shared with the site team in advance of MDA. Instead site teams will be alerted which individuals have been sampled only after they have been visited by a CDD and field worker. Once the identity of a sampled individual has been shared with the site team they have 48 hours in which to deliver the coverage survey and collect a urine sample.
- e) Once a urine sample has been obtained from an individual it must be kept in cold storage and transported to the lab within 12 hours of being collected. Upon arrival at the lab two aliquots of a minimum volume of 7ml will be created and stored at -20°C. Procedures outlined in *SOP_706 Stool receipt aliquoting and storage* will be adapted in order to process the samples.

6.2. Survey preparation

- a) In advance of the Survey, the field team should conduct a sensitization visit or phone call to village leaders to ensure that they are aware of the survey in advance of the survey team's visit
- b) An age-stratified sample of five individuals (1 Pre-SAC, 1 SAC, 3 adults) from each cluster will be selected centrally to participate in the Survey. A replacement sample list of ten individuals (2 Pre-SAC, 2 SAC, 6 adults) also be selected.
 - i. For individuals under 19 years in both control and intervention clusters (who will be assumed to be treated through NDD for the most case) they will need to be visited within 47 hours of NDD. The sample lists for these individuals will be combined with the reserve lists and released to the site team on the day of NDD. Individuals on this combined list will be ranked according to their list of origin (stage 1=original sampling list, stage 2=1st reserve list, stage 3=2nd reserve list).

Field supervisors should work their way down these combined lists attempting to sample all individuals within an age stratification bracket in a stage before moving on to individuals from the following stages.

- ii. For adults in control clusters the sample list will be combined with the reserve sample list to make a combined list of 9 adults per cluster from which three must be sampled. The combined list will be shared with the site team on NDD and study staff will be required to complete the coverage survey and collect a urine sample for three adults per cluster. **For adults in the control cluster** it's important to note that **study staff should not aim to collect all samples within the first two days of MDA** but instead space out data collection so it extends until towards the end of MDA. Sample collection from adults in control clusters should broadly match the rate of sample collection from adults in intervention clusters
- iii. For Intervention clusters the adult sample list for the survey will not be shared with the site team prior to MDA treatment. Instead the sample list will be combined with the reserve list and released to the site team on an individual-by-individual basis following appearance on the treatment database through the MDA Treatment Log. Following identification of a sampled individual by the central team the site team then has up to 48 hours from the stated visit time to complete the coverage survey and collect a urine sample.

Study arm	Sampling list	Sampling list shared with site team	Data collection activities begin	Data collection activities finish
Intervention clusters	Adults (n=60)	Following start of MDA on individual by individual basis	Two hours after an individual's household has been visited by DW3 staff	Within 48 hours of DW3 staff visiting household
	Pre-SAC + SAC (n=40)	On NDD	NDD+1	10am on NDD+2
Control clusters	Adults (n=60)	On NDD	NDD+1	End of CWMDA
	Pre-SAC + SAC (n=40)	On NDD	NDD+1	10am on NDD+2

- c) Urine-collection kits should be prepared in advance so that these can be ready to be taken to the field at short-notice. To prepare the kits:
 - i. Offer tissue and if requested tear off tissue roll, counting several squares per kit
 - ii. Include a 50ml container
 - iii. Compile in a small opaque bag.
- d) For individuals in control clusters and pre-SAC and SAC in intervention clusters barcode stickers should be printed as soon as the sampling lists are shared with the site team. For adults in intervention clusters the barcode stickers should be printed following the identification of a sampled individual. The barcode stickers will contain the 9-digit participant ID and only one label should be printed per individual. The field officer should take the barcode stickers for the individuals they will be visiting that day.
- e) For treated individuals in both study arms the site teams should make sure to arrive at households no later than 47 hours after reported treatment (designated as 10am

on NDD for all pre-SAC and SAC) so as to allow the potential for an hour waiting period between supplying the container and receiving a sample.

- f) For adults in intervention clusters sampled individuals will appear on treatment lists immediately after an MDA log form has been submitted for their household, regardless or not whether they were treated or present during this visit. However, individuals should not be visited before at least two hours have passed since their household was visited by DeWorm3 staff for treatment.
- g) Field officers should ensure they have the latest version of the SurveyCTO Treatment Coverage Urine Survey on their smartphone, and that the smartphone is fully charged.

6.3. Locating and approaching the Individual

- a) Locate the intended household using the Treatment Coverage Urine Survey Participant Sample List. For each sampled participant, information collected at the census will be provided (Admin levels including village, Household ID, Household Head Name, Household Address/Information, Household Phone Number, Sampled Individual Name(s), Sampled Individual age, Sampled Individual sex, Sampled Individual ID.
- b) Open the SurveyCTO Treatment Coverage Urine Survey form. Proceed through the form selecting the administrative level you are in, followed by the correct field officer name. After selecting the village that the individual is located in you will be presented with a list of individuals and their corresponding households. Select the relevant individual from this list.
- c) Once you have selected an individual form will ask you to confirm the activity that you are visiting the household for. The only option will be [Coverage survey and collecting urine sample]. Select this and proceed. After this the form will display the participant's individual and household information for you to confirm. If this is correct proceed and use the Google map to navigate to the household if needed.
- d) Upon arrival at the household, first confirm that the individual is present at the household. If they are not present arrange a time to return to the household when they will be available and then save and finalise the form. Make sure that the return visit does not extend more than 47 hours after treatment.
- e) Following this, ask if the household's DeWorm3 Study Card is available. If the card is available, ask to see it and scan the barcode on the card. If not, select [No] and indicate why the card is not available.
- f) If the card is not available, select the method of entry for the Household ID you will use. The preferred option is scanning the Household's copy of the consent form, then the extra sticker in the census log you have taken to the field, and the last option is entering the ID manually from the participant sample list you have taken to the field.

6.4. Eligibility and informed consent

- a) Once you have entered the individual's ID and received confirmation this is correct and you have confirmed that the individual's cluster and village information is correct proceed with assessing eligibility and seeking consent.
- b) Explain that you have come to ask the individual some questions about the NDD/MDA and that you would like to ask them a few questions about their recent experience of the treatment procedures and that you would also like to request a urine sample.

- c) The individuals on the list should either have been part of NDD or, if they are over 18 years of age and in an intervention cluster, visited during community-wide MDA. Individuals will not have been aware of this data collection activity during the treatment activities.
- d) It should be confirmed that the individual:
 - i. is older than 24 months of age
 - ii. was able to swallow an entire tablet without requiring it to be crushed
- e) Individuals aged under 19 years who were not treated in NDD and adults logged on the SurveyCTO Treatment Log during MDA who are in an intervention cluster but were not necessarily treated are still eligible for the Urine Sample Coverage Survey. These individuals should not be excluded on the grounds of not being treated based on their answers given to the coverage survey questions.

6.5. Consent Procedures

- a) If assent/consent is refused, the individual is not eligible and will need to be replaced.
- b) Written informed consent will be required from individuals aged 18 years or greater. Parental/guardian consent will be required for any individuals under 18 years. If the child is aged 7-18 years written assent will be required from them in addition to the parental/guardian consent.
- c) If the potential participant is 18 years or above, only they are required to be present to consent. If the potential participant is below 18 years a caregiver must be present to participate during the entirety of the consenting/assenting process.
- d) For participants aged between 2 and 7 years, the caregiver must provide informed consent for their participation. For participants of age between 7 and 11 years the child must provide verbal assent in presence of the parent/caregiver and the parent/caregiver must provide informed consent for their participation mentioning that their child has consented to participate. For participant between 12 and 17 years the child must provide informed written assent in addition to parental/caregiver consent.
- e) First determine which language the individual or their caregiver prefers and whether the individual/caregiver can read and write.
- f) Verbally explain to the potential participant and/or their caregiver the purpose of the study in general, study requirements, and the risks and benefits of study participation. This is just a single timepoint survey.
- g) Participants/caregivers will be told that participation in the Treatment Coverage Urine Survey is completely voluntary and if they do not feel comfortable, they need not participate. If the potential participant or their caregiver is interested in participating in the Treatment Coverage Urine Survey and is able to read, give him/her a Treatment Coverage Urine Survey Consent Form in their preferred language to review.
- h) Read the Consent Form to the participant/caregiver and answer any questions that the participant/caregiver has regarding the study or study participation.
- i) If the participant/caregiver agrees to participate, she/he will be invited to sign the Consent Form.
- j) If the participant/caregiver agrees to participate, she/he will be invited to sign the Consent/assent Form.
- k) If the potential participant is less than 18 years of age, a caregiver must be present and participate during the entirety of the consenting/assenting process for the

- participant to be enrolled in the Urine sample coverage survey and provide consent.
- l) If the participant is a child 7 to 11 years of age, explain about the study in simple language in the presence of their parent/caregiver. After explaining the study, answer any questions that the child has and confirm verbal consent.
 - m) If the participant is a child 12 to 17 years of age, read the Assent Form to the participant. After reading the form, answer any questions that the child has. If the child agrees to participate in the survey, he/she will be invited to sign the Assent Form.
 - n) After consent/assent is provided, sign the Consent and Assent Forms. Ensure that the parent/caregiver has already signed an informed consent form for the child to participate.
 - o) If the participant has a significant intellectual disability or is deaf/dumb they take on the same status as a child less than 7. If they are able to assent please document this as well as consent from the primary caregiver and if unable to assent, collect consent from the primary caregiver. This applies whether the participant is a child or an adult. The primary caregiver will answer the questions on the participant's behalf. Document such a case in the notes section at the end of the survey.
 - p) If the participant and/or caregiver is unable to sign the Consent or Assent Forms, she/he will apply a thumbprint using the inkpad. However, her/his name must be written on the same page by an impartial witness. The impartial witness must be a literate adult (aged 18 years or above) of the participant/caregiver's choice (not study staff) who has sat through the consenting process, can read the information provided and sign their own name.
 - q) Provide two copies of the Consent and Assent Forms for the participant/caregiver to sign. The participant will be offered one copy and the other copy will be kept and placed in the binder for filing in the office.
 - r) If the potential participant/caregiver is reluctant to sign the Consent Form, then ask her/him if she/he has questions that need to be clarified.
 - s) If the potential participant still indicates unwillingness to participate in the study, then thank her/him for their time and assure him/her that this will not affect their access to MDA in the future.
 - t) **If the participant and/or the caregiver of the participant (if required) is *not present*** at the house to consent and to participate in the Urine Sample Coverage Survey select [No, unable to answer at this time] in the Form. Save and finalise the form now. Schedule a time to return when the participant (and or their guardian) will be home. Mark on the Treatment Coverage Urine Survey Participant Sample List that the household has been visited for the first time and a repeat visit is required.
 - u) **If the participant and/or the caregiver of the participant (if required) *refuses consent*** thank them for their time and then Save and finalise the Form.
 - v) **If the participant and/or the caregiver of the participant (if required) is *present*** select [Yes, consented] and continue with the survey.

6.6. Coverage survey questions

- a) During survey administration, it is very important to stress the difference between being offered/given the tablet as opposed to swallowing the tablet. These are separate questions on the survey.
- b) As individuals may have been treated by the school programme or the community programme, the questions start from the premise of did someone give you a tablet like this so that whichever programme they received it from, they should be able

to answer the questions in the same way.

- c) Produce the ziplock bag with the albendazole tablets in and hold this out to the individual and ask “Did someone give you a tablet like this in the past month to treat worms (at home, at school or in the community)?” treatment could have been in any of these locations depending on whether the individual was treated in the NDD or DeWorm3 community programme.
- d) If they say no, the follow up question will ask why they did not receive the tablet, with multiple options
- e) If the individual says “yes” someone gave them a tablet, the next question will ask whether they swallowed the tablet.
- f) **If they say yes (they did swallow the tablet)**, the follow up question will ask why they did swallow the tablet, with multiple options (select the primary reason). Then the survey will ask:
 - 1. Why did you swallow the tablet?
 - 2. Did you swallow the tablet in front of the person who gave it to you?
 - 3. Who gave the tablet? e.g. teacher, health staff etc.
 - 4. Where did they give you the tablet? e.g. at home at school etc.
- g) **If they say no (they did not swallow the tablet)**, the follow up question will ask why they did not swallow the tablet, with multiple options. Then the survey will ask:
 - 1. Why did you not swallow the tablet?
 - 2. Who gave the tablet? e.g. teacher, health staff etc.
 - 3. Where did they give you the tablet? e.g. at home at school etc.
- h) For PSAC and SAC individuals the form will ask what time of the day they were treated if they indicate that they were treated at school. The responses are separated into 5 distinct periods that reflect the school day.

6.7. Urine sample collection

- a) Following the coverage questions participants will be asked to provide a urine sample to be sent to the lab for storage for subsequent testing.
- b) Introduce the Urine Collection Kit materials to the participant (Tissue roll, 50ml container, small opaque bag). Explain the contents of the Urine Collection Kit:
 - i. The tissue roll is for wiping any spillage
 - ii. The 50ml container will be used to carry the urine sample back to the laboratory
 - iii. The bag is to protect their privacy
- c) Apply the appropriate barcode sticker with the word “Urine” to the lid of the container **before you give the pot to the participant.**
- d) **It is essential that the participant collect the urine sample at the time of the visit of the field officer.** In situations where the participant is not able to do so, as a last resort, the field officer can leave the Urine Collection Kit with the participant and return after a maximum of one hour to collect the sample. The barcode must be placed on the container prior to giving it to the participant.
- e) Do not stick the barcode to the side of the urine container, as this is a curved surface and cannot be scanned. Do not stick it to the base of the pot, as if this is put down on a muddy/wet surface the barcode will be soiled.

- f) Write the participant's name on a sticker using permanent marker/ball point pen and paste it on the side of the urine container.
- g) Give the participant the following instructions:
 - i. Ask the participant to go to the place where they usually urinate, preferably a toilet facility. If not, wherever they would usually go.
 - ii. They should collect enough urine to fill at least two thirds of the container (you can mark a line on the container to indicate the amount required). Then they put the lid on tightly.
 - iii. Inform them to use the tissue roll for wiping any spillage
 - iv. Once the collection is complete they should dispose of tissue roll in the latrine facility if available.
 - v. The collected urine in the container should be placed into the opaque bag and handed to you.
- h) A glove should be worn when receiving the urine from the participant, although there should be no direct contact with the urine as it will be in a container within a bag.
- i) When the participant hands over the container, discretely check the sample (without removing the lid). Note down any comments in the SurveyCTO Form.
- j) Scan the ID on the urine container into the Form. If the ID is soiled and cannot be scanned, enter the ID manually.
- k) If the ID does not match the ID of the participant logged in the survey, this will be flagged and you will not be able to proceed.
- l) Once collected from the participant and logged, place the urine container in the cooler box ready to transport to the laboratory. Save and finalise the form.
- m) All samples should be delivered to the lab within 12 hours of being collected by the participant. Here they will be aliquoted into two 10ml tubes and stored at -20°C

6.8. Returning to collect a urine sample later

- a) In situations where the participant is not able to provide a sample at the time of the field supervisor's visit, as a last resort, the field supervisor can leave the Urine Collection Kit with the participant and return after a maximum of one hour to collect the sample. In this instance select [no] when asked if the respondent is able to produce a urine sample. Apply the sticker to the side of the container and explain the collection process (as outlined in section 6.7 points d – g). After applying the sticker to the container the form will ask you to scan the barcode. Following this proceed to save and finalise the form. You should then submit the form and wait at least 20 minutes before returning to the household so that the server has time to update the individual's status.
- b) Before leaving the pot with the individual insist the urine must be fresh, not from another day (for those who do not have toilets and can identify a previously collected urine). Also emphasize the importance of the urine being collected being from the same individual who was sampled and was administered the albendazole.
- c) When returning to a household to collect the urine sample, open the SurveyCTO Treatment Coverage Urine Survey and follow the steps outlined in 6.3 to confirm the identity of the individual. After selecting the correct household from the list indicate the purpose of the visit. If a container has already been left for the individual to provide a urine sample then the only option available will be [Returning to collect urine sample]. Select this and then proceed to the household, following directions if required.

- a. When receiving the sample from the participant a glove should be worn, although there should be no direct contact with the urine as it will be in a container within a bag.
- b. When the participant hands over the container, discretely check the sample (without removing the lid). Note down any comments in the SurveyCTO Form.
- d) In the event that the participant is not present at this return visit, or has been unable to provide a urine sample they should be recorded as being unable to provide a sample and excluded from the survey. They will be replaced by an individual from the next sampling stage within the same age stratification bracket.

6.9. Survey completion

- a) Save and finalise the SurveyCTO form.
- b) Ask the participants if they have any further questions and thank them for their participation.

6.10. Replacing Treatment Coverage Urine Survey participants

- a) Wherever any of the exclusion criteria are met, an individual may be replaced by someone on the list from the next stage (e.g. stage 2) this will appear next to their name on the paper list and in the SurveyCTO form. The replacement individual must be within the same age bracket. The exclusion criteria include: individuals who refuse consent/assent, are unavailable to provide a urine sample within the 48-hour post-treatment period or are unable to provide a urine sample within one hour of the study staff visiting.
- b) Participants must be visited and a survey logged before they can be replaced in the survey. In the case that an individual is not present at the household at the point of first contact they should be visited a further two times before they are replaced. However, if a member of the sampled individual's household indicates that they will not be present until after 48 hours since treatment have elapsed the individual may be replaced without further repeat visits. Where this is the case you should record this in the form notes before saving and finalising the form.
- b) For individuals in control clusters and pre-SAC and SAC in intervention clusters, sampled individuals on the combined sample list are ranked according to the order in which they should be sampled. When replacing individuals you should work down the list until the required number of individuals within each age stratification bracket have been sampled.