TROPICAL DATA

Tropical Data trachoma survey protocol guide

Version 5, November 2021

Before starting your protocol, check whether you have previous protocols that you could use as a template and adapt.

Please also look at our accompanying "Tropical Data Protocol Writing Guide" YouTube video: https://www.youtube.com/watch?v=f2X75ZaWvpc

Below is a suggested list of headings and content to include when developing your Tropical Data trachoma survey protocol.

1. **Title page**

- Country
- Districts to be surveyed
- Type of survey (baseline, impact, surveillance, trachomatous trichiasis (TT)-only)
- Date and version of protocol
- Names and contact details of applicant(s) and key partners

2. **Introduction/Background**[1]

- Trachoma is the leading infectious cause of blindness worldwide.
- The prevalence targets for elimination are: trachomatous inflammation—follicular (TF) <5% in 1–9-year-olds, and TT unknown to the health system <0.2% in adults aged ≥15 years.
- Keep focus on the districts to be surveyed and their current and past situation.

3. **Rationale/justification for trachoma survey in this/these district(s)**

- Explain why this specific survey is appropriate to be conducted in this/these district(s) at this time.
- Timing of surveys:
    - Impact surveys should be undertaken 6-12 months after the last round of MDA, as per last survey prevalence indications.
    - Surveillance surveys should be done at least 24 months after the most recent impact survey showed that TF prevalence in 1–9-year-olds was <5%.
    - Table 1 below illustrates how programmes can present the necessary information to ensure correct timing. Please note, your district reports from previous Tropical Data-supported surveys in the Evaluation Units (EUs) have the survey completion dates.

[1] Please remember that Tropical Data is not WHO-led. Instead, Tropical Data is a consortium of partners (International Trachoma Initiative, London School of Hygiene & Tropical Medicine, RTI International, Sightsavers) that supports health ministries conduct globally standardised, epidemiologically robust, prevalence surveys that conform to WHO recommendations.

Region/ Province	District/ sub-district	Total estimated population	Estimated population size of 1-9-year-olds	Number of Evaluation Units	TF prevalence at most recent survey (Date & Type of survey)	Month & year last MDA was completed	Planned Survey Type	Planned Survey Month & Year
North	North East	150,000	45,000	1	2.5% (Impact, Dec 2018)	May 2018	Surveillance	Jan 2021*
East	Southern 1	100,000	35,000	1	7.7% (Baseline, June 2019)	March 2020	Impact	Jan 2021**
East	Southern 2	150,000	50,000		12.5% (Baseline, June 2019)	Last round planned March 2022	Impact	Jan 2023**

* At least 24 months after impact survey with TF<5%

**6-12 months after last MDA round

4. Aim

For example:

- *Baseline surveys:* To determine the baseline prevalence of trachoma in [name districts and country].
- *Impact surveys:* To determine whether continued trachoma interventions are needed in [name districts and country].
- *Surveillance surveys:* To determine if interventions against trachoma need to be re-introduced in [name districts and country] or whether prevalence of trachoma has been maintained below the elimination threshold.
- *TT-only surveys:* To determine the prevalence of trachomatous trichiasis (TT) in [name districts and country].

5. Specific objectives

For example:

- To measure the prevalence of TF among children aged 1–9-year-olds.
- To measure the prevalence of TT among adults aged ≥15 years.
- To determine household-level availability of improved water access and sanitation facilities.

6. Methods

- **Survey population**

Include details on districts and EUs to be surveyed, including population sizes (see Table 1)[2].

- If a district is split into two or more EUs due to large population size:
    - Please indicate how the district is being split (e.g. using a road as a natural demarcation), and the population of each EU.
    - It is also important to ensure that programmatic decisions can be implemented at the sub-district EU level. For example, if District A1 has a TF prevalence <5% but District A2 has TF >5%, will it be programmatically possible to implement MDA to half the district but not the other half?
- For multiple districts to be combined into one EU, they should be geographically contiguous, socio-economically similar, and it should make sense geo-politically and programmatically on the ground.

If possible, please also provide maps of the districts to be surveyed, as this can be really helpful if splits have happened, or if our files used to make maps are not up-to-date.

- **Sample size calculation**

The sample size calculation, according to the single population proportion for precision formula, is:

$$n = DEFF \times (z^2 \times p(1-p)/c^2) \times e$$

[where DEFF is the design effect; z is the standard deviation corresponding to 95% confidence intervals; p is the expected prevalence; c is the absolute precision; e is an inflation factor to account for non-response[3]].

Values to input into this formula for baseline, impact, surveillance and TT-only surveys are provided in Table 2 below. Baseline surveys may be powered to either detect a TF prevalence of 10% (±3%) or 4% (±2%), depending on the expected TF prevalence (perhaps based on historical data, current prevalence in neighbouring districts, and/or geographical, socio-economic and political context).

[2] In general, an Evaluation Unit (EU) is a district, which for trachoma elimination purposes WHO defines as "the normal administrative unit for health care management, consisting of a population unit between 100,000–250,000 persons" (https://apps.who.int/iris/handle/10665/43405).

[3] An arbitrary inflation factor of 1.2 is used, unless your previous work enables you to use an actual non-response rate for the population and setting.

Table 2. Inputs to calculate sample size			
Variable	**Input**		
	Baseline	**Baseline, impact and surveillance**	**TT-only**
Design Effect	3.69[4]	2.63[4]	1.47[4,5]
Standard deviation for 95% confidence interval	1.96	1.96	1.96
Expected prevalence (%)[6]	10	4	0.2
Absolute precision (%)	3	2	0.2
Number to examine	1418	970	2818
Non-response rate inflation factor[3]	1.2	1.2	1.2
Targeted number to enumerate[7]	1701	1164	3382

If EU population size is <100,000, correction for a small, finite population can be applied to the sample size calculation. Tropical Data epidemiologists can support you with this.

- **Number of clusters and households to select[8,9,10]**

For baseline, impact and surveillance surveys, the number of clusters, *c*, needed per EU is determined by dividing the total targeted number of children aged 1–9 years to be enumerated by ([number of households per cluster]x[mean number of 1–9-year-olds per household]). There should be a minimum of 20 clusters, so if *c*<20, 20 clusters should be selected anyway. If *c*, determined by the above formula, is ≥30, 30 clusters should be used[5].

For TT-only surveys, the number of clusters, *c*, that would ideally be included is given by $c = (3382)/(h \times a)$, where *h* is the number of households that can be examined by one team in one day, and *a* is the expected mean number of adults resident in each household, as determined by the most recent census or recent population-based trachoma survey experience. There should be a

[4] WHO. Design parameters for population-based trachoma prevalence surveys. https://apps.who.int/iris/handle/10665/275523; 2018.
[5] WHO. Design and validation of a trachomatous trichiasis-only survey. https://apps.who.int/iris/handle/10665/259815; 2017.
[6] For baseline, impact and surveillance surveys, this is the expected TF prevalence. For TT-only surveys, this is the expected TT prevalence.
[7] For baseline, impact and surveillance surveys, this is the number of children aged 1-9 years to enumerate. For TT-only surveys, this is the number of adults aged ≥15 years to enumerate.
[8] It is strongly recommended that a fixed number of households be recruited per cluster. Therefore, programmes should first set the number of households to be visited per cluster as the number of households that one team (one grader plus one recorder for prevalence surveys; one recorder/grader for TT-only surveys) can reliably see in a single day of fieldwork: this varies from one country to another based on how difficult it is to move from one household to another in rural communities, due to distance between households and the terrain.
[9] When doing the calculation, please do not round up or down the mean number of 1–9-year-olds per household, or the product of ([number of households per cluster]x[mean number of 1–9-year-olds per household]). However, when the cluster calculation has been completed, please round up to the next whole number, to help ensure the sample size is met. For example, if the calculation result is 23.4 clusters, round up to 24 clusters to survey.
[10] If you plan on surveying <30 clusters, please let the Tropical Data team know if you would like us to check the demographic data from previous surveys in the specific EUs during protocol development, to help make sure sufficient clusters are selected.

minimum of 20 clusters, so if *c*<20, 20 clusters should be selected anyway. If *c*, determined by the above formula, is ≥30, 30 clusters should be used[5].

If in baseline, impact and surveillance surveys the calculated minimum number of clusters to reach the sample size is less than 30 but you would like more confidence in the TT prevalence estimates, you could increase the number of clusters to 30. Also, please note that the WHO TT-only survey protocol[5] points out that even if the sample size of 2818 adults is not reached with 30 clusters, 30 clusters provides acceptable precision around the TT prevalence estimate.

Table 3. Inputs required to calculate number of clusters per EU

Variable	Input
Sample size (target number to enumerate)	• 1701 for TF 10% (±3%) • 1164 for TF 4% (±2%) • 3382 for TT-only surveys
Number of households to survey per cluster	The number of households that can be examined by one team in one day
Mean number of individuals per household	• 1–9-year-olds for baseline, impact and surveillance surveys • ≥15-year-olds for TT-only surveys

- **Survey team composition and roles**

- **Training**

Graders and recorders should have completed and be certified according to the latest Tropical Data training system[11,12].

- **Sampling approach (cluster and household selection)**

Two-stage cluster random sampling. Sampling of clusters within the EU, and sampling of households within the cluster, should be undertaken to adhere to the principles of equal probability random sampling, or its best approximation given the circumstances.

For first-stage cluster sampling, where cluster-level population estimates are known in advance, probability of cluster selection should be proportional to population size[13].

It is helpful to indicate at the protocol writing stage whether you would like Tropical Data support with cluster selection. In addition, if you are aware of any potential issues with cluster accessibility, such as insecurity or flooding, it would be helpful to say this so that mitigation plans can be incorporated in the protocol and thought through before the teams are in the field.

Household selection within clusters will vary from country to country, with the most common methods being simple random sampling and systematic sampling when there is a complete list of

[11] Courtright P, MacArthur C, Macleod CK, Dejene M, Gass K, Harding-Esch EM, Jimenez C,Lewallen S, Mpyet C, Pavluck AL, West SK, Willis R, Solomon AW (2019). Tropical Data: training system for trachoma prevalence surveys (version 3). International Coalition for Trachoma Control: London. http://tropicaldata.knowledgeowl.com/help/training-system-for-trachoma-prevalence-surveys.

[12] Courtright P, Flueckiger RM, Harding-Esch EM, Lewallen S, Solomon AW (2019). Tropical Data: training system for trachomatous trichiasis population-based prevalence surveys (version 2). International Coalition for Trachoma Control: London. http://tropical-data-fr.knowledgeowl.com/help/training-for-mapping-of-trachomatous-trichiasis.

[13] WHO, Trachoma control: A guide for programme managers.2006. https://apps.who.int/iris/handle/10665/43405

households at the cluster level, and compact segment sampling when there is not[14]. During fieldwork, it is the number of households per cluster that should be targeted, not the number of individuals-to-be-examined or enumerated that was indicated by the sample size calculation. If the required number of households are not present in any given selected cluster, the remaining households can be selected, using the same household selection method, from the closest adjacent cluster. If compact segment sampling is used, teams should survey all households in the segment, regardless of whether this is more or fewer than the target number of households.

- **Data collection, management and ownership**

Data are entered into the Tropical Data app, on an Android smartphone.

Include details on the trachoma grading (including examination methods) and questionnaire data collection, data management, and data ownership. The "Household Form" and "Census And Examination Findings Form" are available on the Tropical Data resources page, if you would like to include these as protocol appendices.

For baseline, impact and surveillance surveys, at each household, teams should examine both eyes of each resident aged one year and above for the clinical signs trichiasis (upper and lower eyelid, separately), TF and trachomatous inflammation—intense (TI). Follicle size guides, routinely provided by Tropical Data, should be used for the diagnosis of TF[15]. Where trichiasis is recorded as being present in an eye (upper and/or lower eyelid), the presence or absence of trachomatous scarring (TS) in the upper tarsal conjunctiva of the same eye should also be recorded, and the participant should be asked if they have ever been offered management for their trichiasis by a healthcare worker. GPS and WASH (water, sanitation and hygiene) data[16] are collected at the household level.

For TT-only surveys, generally a single individual functions as both grader and recorder, and no WASH data are collected. At each household, teams should examine each person aged ≥15 years for the clinical signs of trichiasis (upper and lower eyelid, separately). Where trichiasis is recorded as being present in an eye (upper and/or lower eyelid), the presence or absence of TS in the upper tarsal conjunctiva of the same eye should also be recorded, and the participant should be asked if they have ever been offered management for their trichiasis by a healthcare worker.

To help with quality assurance of the health management responses and to ascertain if the participant has had trichiasis surgery, we recommend that the grader should also check for the presence of a surgical scar (see Appendix for suggested step-by step methodology):

- Grader observes trichiasis in participant
- Grader checks/pays attention to presence of trichiasis surgical scar while everting eyelid to look for TF, TI and TS
- Grader asks participant health management questions
- Grader asks further probing questions if the participant answers yes to having received surgery but the grader did not see a surgical scar, or the participant answers no to having received surgery but the grader sees a surgical scar.

[14] https://www.futurelearn.com/courses/eliminating-trachoma/3/steps/236969, https://apps.who.int/iris/handle/10665/43405, and Turner *et al.* https://doi.org/10.1093/ije/25.1.198

[15] Solomon AW, Le Mesurier RT, Williams WJ. A diagnostic instrument to help field graders evaluate active trachoma. Ophthalmic Epidemiol. 2018 Oct-Dec;25(5-6):399-402. doi: 10.1080/09286586.2018.1500616. Epub 2018 Aug 1. PMID: 30067432; PMCID: PMC6850902.

[16] WASH variables are in-line with the WHO/UNICEF Joint Monitoring Programme for Water Supply, Sanitation and Hygiene (JMP) core questions for households sanitation and hygiene ladder classification (https://washdata.org/monitoring/methods/core-questions)

Teams should return to the household once at the end of the day to try to examine household members from the target age-group (1–9-year-olds for baseline, impact and surveillance surveys; ≥15-year-olds for TT-only surveys) who were absent at the initial time of examination.

The Tropical Data team will support data collection and management by providing: Near-real-time data cleaning using automated data cleaning algorithms and a dedicated data team, enabled by automatic, encrypted data upload to a secure central server, facilitating feedback to teams whilst in the field; Standardised data analyses using automated algorithms and/or specialist, objective data managers, ensuring all surveys have the same outputs; Data review by specialist data managers in collaboration with one or more designated health ministry personnel; Prevalence estimates to inform programme planning.

All data collected using Tropical Data tools are owned by the respective health ministries[17].

7. Ethical considerations

Include details on any ethics committee approvals, methods for obtaining consent, and provisions in place to treat individuals with active trachoma and manage trichiasis cases. *Verbal consent for examination is routinely recorded in the Android phones*. Unless required by national ethical committees, it should not be necessary to have paper-based forms. Names and ages of individuals are recorded, as these facilitate identification of individuals for clinical examination.

It might also be advisable to add a paragraph on Covid-19 mitigations. Here are some resources that may be of help: WHO interim guidance (https://www.who.int/publications/i/item/WHO-2019-nCoV-neglected-tropical-diseases-2020-1), Sightsavers RAMA tool (https://ntd-sightsavers.hub.arcgis.com/search?tags=covid), and USAID, Act to End NTDs | East, and Act to End NTDs | West guidance (Trachoma Surveys: Practical Approaches to Implementing WHO Guidance for Neglected Tropical Disease (NTD) Programs in the Context of COVID-19 | NTD Toolbox).

8. Supervision and coordination

If field teams encounter any challenges that result in deviations from approved protocol, such as inaccessible clusters or issues with the smartphone, we ask that the team leader or survey coordinator contacts the Tropical Data team as soon as possible so that appropriate guidance and support can be provided.

9. Dissemination

We would like to encourage international dissemination of the data, including at conferences and in peer-reviewed publications. Tropical Data has produced a virtual workshop on writing trachoma survey publications[18].

10. Materials required

Tropical Data will routinely provide:

- Loupes
- Follicle size guides
- Android phones

11. Timeline

12. Budget

13. References

[17] Further details regarding the Tropical Data data collection and management processes can be found in "Tropical Data News, December 2017": http://tropicaldata.knowledgeowl.com/help/december-2017

[18] English: https://www.youtube.com/watch?v=a1WYWMyGQdY&list=PLqgTLewOhqRLjrjQyYV1NfqveEircImlP

Appendix: Trichiasis surgical scar acsertainment process

To help with quality assurance of the health management responses, the grader will also check for the presence of surgical scar:

- Grader observes trichiasis in participant
- Grader checks/pays attention to presence of trichiasis surgical scar while everting eyelid to look for TF, TI & TS
- Grader asks participant health management questions

    - **If participant answers yes to having received surgery, but grader did not see a surgical scar,** a discussion is held to confirm it was trichiasis surgery. Appropriate questions to ask would include:
        - "Do you remember why you had the surgery – was it because you had eyelashes rubbing against the eyeball (painful), or because your eyesight gradually deteriorated without pain?" [If it was without pain, it is more likely to have been due to glaucoma, cataract or pterygium which are generally painless)
        - "Did you get an injection into the eyelid before surgery?" [A patient would likely not easily forget if they got an injection into the eyelid. This question would also help us distinguish from other management intervention such as epilation.]

    - **If participant answers no to having received surgery, but grader sees a surgical scar,** a discussion is held to confirm whether trichiasis surgery took place. Appropriate questions to ask would include:
        - "It looks as though you have a surgical scar in this eyelid. Do you remember having had surgery?"
        - **If NO:**
            - The grader should use their discretion. The usual decision should probably be to record the eyelid as not having previously had trichiasis surgery, unless the scar looks very clearly to be the result of surgery to correct trichiasis and the examiner has some reason to suspect that the patient is unwilling or unable to recall a previous operation.
        - **If YES:**
            - "Do you remember why you had the surgery – was it because you had eyelashes rubbing against the eyeball (painful), or because your eyesight gradually deteriorated without pain?" [If it was without pain, it is more likely to have been due to glaucoma, cataract or pterygium which are generally painless)
            - "Did you get an injection into the eyelid before surgery?" [A patient would likely not easily forget if they got an injection into the eyelid. This question would also help us distinguish from other management intervention such as epilation.]
            - If grader is satisfied it was trichiasis surgery, they record the participant as having had trichiasis surgery, even when they are unable to observe a surgical scar.