WORLD HEALTH ORGANIZATION
STRATEGIC AND TECHNICAL ADVISORY GROUP
FOR NEGLECTED TROPICAL DISEASES

WORKING GROUP ON MONITORING AND EVALUATION

DESIGN PARAMETERS FOR POPULATION-BASED TRACHOMA PREVALENCE SURVEYS

World Health Organization

Design parameters for population-based trachoma prevalence surveys

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Contents

Acknowledgements

About this document

This document presents (i) the principles important to the design of trachoma prevalence surveys conducted after interventions intended to eliminate the disease as a public health problem, and (ii) WHO recommendations for their implementation. The intended audience is technical units of health ministries of trachoma-endemic countries and their supporting partners.

1. Background

1.1 Trachoma results from infection with particular strains *(1)* of the bacterium *Chlamydia trachomatis*, causing blindness in the world's poorest people *(2)*. In 1996, a World Health Organization (WHO) Alliance was established to support elimination of the disease as a public health problem[1] by 2020 *(3)*. Decisions on where and how to implement the "SAFE" (surgery, antibiotics, facial cleanliness, environmental improvement) strategy for elimination *(4)* and on whether or not elimination has been achieved *(5)* rely on estimates of the prevalence of disease.

1.2 The gold-standard approach for estimating disease prevalence is a population-based prevalence survey (PBPS), adequately powered for the disease of interest. In an effort to stretch scarce resources, since 1996, various cheaper and cruder methods have been designed to assess the burden of trachoma and the potential need for interventions against it, including trachoma rapid assessment *(6)*, acceptance sampling trachoma rapid assessment *(7)* and integrated threshold mapping *(8, 9)*. Each of these methods has epidemiological drawbacks accompanying its lower cost *(10–12)*. Robust prevalence estimates are important for programmes wishing to establish whether mass drug administration of antibiotics should begin [at baseline survey *(4)*] or could be safely discontinued [at impact survey *(13)*], or to determine whether the disease has recrudesced beyond elimination thresholds after cessation of antibiotic mass drug administration [at pre-validation surveillance survey[2] *(13)*]. PBPSs are used to generate such estimates and are usually performed through cluster sampling.

1.3 Baseline surveys have now been mostly completed in suspected trachoma-endemic populations worldwide using a highly standardized PBPS approach *(14)* consistent with recommendations previously published by WHO *(4)*. The current document provides WHO recommendations, with justification, for undertaking impact and surveillance surveys. The unprecedented recent expansion of the global trachoma programme *(15, 16)*, which anticipates a parallel, trailing acceleration in demand for impact and surveillance surveys, warrants urgent dissemination of these recommendations.

2. Methods

2.1 In developing these recommendations, several resources have been employed. First, existing WHO guidance on trachoma prevalence surveys was reviewed using electronic and manual searches of WHO publications on trachoma located, respectively, on the WHO website and in the personal collections of those preparing this document. Second, basic statistical principles were applied to calculate sample size requirements for various epidemiological scenarios.

2.2 To help parameterize the sample size calculations, use was made of the survey experience acquired from 2012 to 2016 within the Global Trachoma Mapping Project (GTMP) *(14, 17–45)* and the Tropical Data service *(46)*, which has supported national programmes to complete trachoma prevalence surveys since the completion of the GTMP.

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[1] "Elimination as a public health problem" is hereinafter referred to as "elimination".
[2] "Pre-validation surveillance surveys" are hereinafter referred to as "surveillance surveys".

3.   General approach to trachoma prevalence surveys

3.1   Since 1956 *(4, 47–49)*, WHO has recommended the use of PBPSs *(4, 47-49)* to estimate the burden of disease in trachoma-endemic populations and that the techniques used "should be as uniform as possible" *(48)*.

3.2   Data to determine the need or otherwise for implementation of the SAFE strategy are ideally collected at district level *(50)*[1]. It is recommended that districts consist of population units of 100 000–250 000 people *(49)*. Although at baseline, population units larger than districts can be surveyed in order to generate evidence to start a trachoma programme *(49)*, district-level surveys should be undertaken at the impact and surveillance survey stages *(13)*. Because use of the term "district" can create difficulties in contexts where it has a political history or where it is currently employed to describe administrative divisions encompassing populations much larger or smaller than 100 000–250 000 people, this document refers to the population unit being surveyed as an "evaluation unit" (EU).

4.   Sample size required to reliably estimate active trachoma prevalence

4.1   In impact and surveillance surveys, the most critical question to be answered is whether the EU-level prevalence of trachomatous inflammation—follicular (TF) *(51)* in 1–9-year-olds is < 5%: that is, whether the active trachoma prevalence threshold for eliminating the disease has been achieved *(5)*. In 2010, the 3rd Global Scientific Meeting on Trachoma concluded that this question was best addressed by powering surveys to detect a TF prevalence of 4% with absolute precision of ± 2% *(49)*.

4.2   A recent study *(52)* reviewed data from 261 PBPSs conducted in Ethiopia, Malawi and Nigeria during 2012–2016 with GTMP support. For surveys in which the prevalence of TF in 1–9-year-olds was shown to be 2–6%, the 75th centile of (actual individual-survey) design effects (from smallest to biggest) was 2.63. Using this design effect and the "single population proportion for precision" formula, without referencing the underlying population size of the EU *(53)*, to estimate with 95% confidence an expected TF prevalence of 4% with absolute precision of 2% would require an estimated 970 children aged 1–9 years per survey.

4.3   The median number of 1–9-year-olds examined per first-stage cluster (m) influences the design effect. The value of 2.63 assumes an m of approximately 30. Where m is larger, the design effect is also larger: if m is 37, for example, meta-regression suggests a design effect of 2.71 *(52)*. Correction may also be made for the fact that trachoma surveys are carried out in finite populations, using the assumption that ~25% of the population is aged 1–9 years – a valid general approximation in many of the countries where trachoma remains a public health problem *(54)*. Resulting sample size estimates are shown in Table 1.

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[1] A "district" is defined as "the normal administrative unit for health care management".

4.4   If, at impact survey, there is reason to believe that the TF prevalence is still well above 5%, different calculations may be employed (*Table 1*). In the meta-regression of GTMP data, for surveys in which the TF prevalence was 7–13%, the design effect was calculated to be 3.69 for an *m* of approximately 30, and 3.71 for an *m* of approximately 37 *(52)*. (The use of three significant digits here implies more precision than is possible in real-world survey planning, and should be interpreted as being illustrative rather than prescriptive.)

Table 1. Sample size calculations for estimating the prevalence of trachomatous inflammation—follicular (TF) in different epidemiological scenarios, trachoma impact and surveillance surveys

Estimated EU population (estimated population aged 1–9 years)	Expected [TF_{1-9}] (absolute precision)			
	4% (± 2%) *(49)*		10% (± 3%) *(14)*	
	m^a=27–33 DE=2.63	*m*=34–40 DE=2.71	*m*=27–33 DE=3.69	*m*=34–40 DE=3.71
250 000 (62 500)	956	984	1334	1339
100 000 (25 000)	934	962	1291	1298
50 000 (12 500)	901	926	1228	1234
25 000 (6250)	840	862	1118	1123
10 000 (2500)	700	715	882	885

DE: design effect; EU: evaluation unit; [TF_{1-9}]: prevalence of TF in 1–9-year-olds
[a] Median number of 1–9-year-olds expected to be examined per first-stage cluster.

5.   Sample size required to reliably estimate trachomatous trichiasis prevalence

5.1   Elimination of trachoma *(5)* requires an EU-level prevalence of trachomatous trichiasis unknown to the health system[1] in adults aged ≥ 15 years of < 0.2%.

5.2   Evidence-based sample sizes have recently been determined for trachomatous trichiasis-only surveys. To estimate, with 95% confidence, an expected trachomatous trichiasis prevalence of 0.2% with absolute precision of ± 0.2% and a design effect of 1.47, 2818 adults aged ≥ 15 years should be examined *(55)*. Simulations suggest that even if the calculated sample size of 2818 adults is not achieved, data from 30 first-stage clusters provide acceptable precision.

5.3   In many impact and surveillance surveys primarily designed to estimate the prevalence of TF in 1–9-year-olds, fewer than 30 first-stage clusters are enrolled and fewer than 2818 adults examined. It is not recommended to routinely increase the number of households enrolled in order to ensure examination of 2818 adults in each EU. Rather, the number of households required for the survey should be determined using principles relevant to estimating the TF prevalence (see *section 4*); in selected households, all individuals aged ≥ 1 year who are present in the household and who consent to being examined should be examined. Consideration could be given to increasing the number of first-stage clusters to 30.

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[1] Excludes trichiasis in eyes (i) with post-surgical recurrence, (ii) for which surgery has been refused, or (iii) which are listed for surgery but have not yet received an operation, but for which a surgical date has been set.

5.4   Further work to optimize ways to determine whether the trachomatous trichiasis prevalence target for trachoma elimination has been reached would be helpful.

6.   Sampling approach and field methodology

6.1   Where possible, it is recommended to undertake a PBPS using two-stage cluster sampling. Generally, this involves (i) selection of villages, census enumeration areas or the local equivalent as the first-sampling-stage clusters; and (ii) selection of households as the second-sampling-stage clusters *(4, 14)*.

6.2   It is recommended to recruit a fixed number of households (rather than a fixed number of people or a fixed number of 1–9-year-olds) per first-stage cluster, the rationale being that when minimum numbers of people must be enrolled or examined each day, field teams may resort to convenience sampling as the day draws to a close, to ensure that their targets are met. In contrast, when fixed numbers of households are required, this is less likely, and household selection can be tracked using global positioning system data *(14)*.

6.3   To maximize efficiencies, it is recommended that programmes first set the number of households (*h*) to be visited per first-stage cluster as the number that one team (one grader plus one recorder) can comfortably see in a single day of fieldwork: this will vary from one context to another based on the difficulty of moving from one household to another in rural communities, the distances between households and the geography of the intervening terrain. The number of first-stage clusters needed per EU is then determined by: *sample size* × NRI/($h \times c$), where NRI is the non-response inflator and *c* is the mean number of 1–9-year-olds per household (which is a value derived from the most recent census data). For the NRI, national programmes may wish to draw from their experiences in undertaking trachoma surveys, or use 1.2, the default NRI for the GTMP *(14)*.

6.4   There should be a minimum of 20 first-stage clusters per survey *(56)*, so if the number calculated using the formula in paragraph 6.3 is < 20, then 20 first-stage clusters should be selected. There should be a maximum of 30 first-stage clusters per survey.

6.5   First- and second-stage sampling should be undertaken using methods that equalize, as far as practicable, the probability that any given individual resident aged ≥ 1 year in the EU will be invited to participate. For first-stage sampling, a selection procedure that confers a probability of first-stage cluster selection proportional to the cluster's population size *(4)* should be used, assuming that first-stage cluster-level populations are available; where they are not available, simple random sampling, perhaps with geographical stratification, should be used.

6.6   For second-stage sampling, simple random sampling or systematic sampling can be used if a list of households is available and the first-stage cluster is relatively geographically compact. If either of these conditions is not met, compact segment sampling *(57)* is recommended because its use leads to more objective household selection than commonly-used alternatives such as the random walk *(58)*. Compact segment sampling also allows conclusions to be drawn about the prevalence of the disease within selected segments, which can be useful for secondary analyses of acquired data *(59)*.

6.7   In each selected household, a certified grader (see *section 7*) should examine each consenting resident aged ≥ 1 year for the clinical signs of trichiasis, TF and trachomatous inflammation—intense (TI) *(51)*. When trichiasis is recorded as being present in an eye, (i) the presence or absence of trachomatous scarring (TS) *(51)* should also be recorded *(13, 60)* and (ii) the individual asked if a health worker has ever offered them management of the trichiasis in that eye *(61)*.

6.8   To align with the strategic objectives of *Water, sanitation and hygiene for accelerating and sustaining progress on neglected tropical diseases: a global strategy 2015–2020 (62)*, collection of household-level data on water and sanitation is recommended *(61)*; other data of interest may also be recorded *(63)*, taking advantage of the survey's epidemiological strength.

6.9   Populations of refugees and internally-displaced persons who either come from or settle in trachoma-endemic areas pose specific challenges for the design and implementation of surveys, but these tasks should be approached using the same principles.

7.   Field team training

7.1   Trachoma surveys rely on clinical diagnosis. Inaccurate grading is likely to lead to inappropriate decision-making at EU-level and to unnecessarily prolong or prematurely terminate annual mass drug administration of azithromycin. Intensive training of graders before surveys are conducted, with standardization and certification of TF diagnosis via a formal training cascade *(14)*, is recommended to assure diagnostic accuracy and maximize cross-border data comparability *(64)*. Similar quality assurance for the data recording role is also recommended *(61)*.

8.   Data management

8.1   International systems now exist to facilitate electronic collection of data; cloud-based storage of data; and the review, cleaning and automated analysis of data by independent data managers *(14)*. These systems confer benefits that include high data throughput; industry-standard accessibility, security and redundancy of data; demonstrably objective survey outputs; and opt-in automated linkage (after approval of data by health ministries) to processes for requesting donated azithromycin and epidemiological reporting *(64)*. Regardless of the methods for recording and storing data, use of age standardization (when determining TF prevalence in 1–9-year-olds) and age- and gender-standardization (when determining trichiasis prevalence in ≥ 15-year-olds) is recommended. However, such age- and gender-standardization should *not* be to a common (international) population pyramid, but to a pyramid derived from the most recent census of the population in question – the purpose is to partially correct for the effect of imperfect survey enrolment, as discussed elsewhere *(14, 64)*.

9.   Comment

9.1   Guidance on implementing TT-only surveys is also available separately *(55)*.

9.2   The current document is intended to provide health ministries and their partners with the information needed to plan trachoma impact and surveillance surveys. Surveys following these recommendations should provide data of sufficient quality to populate dossiers claiming elimination of trachoma. Such dossiers could be submitted to WHO without concern that data quality might lead to the claim of elimination not being validated *(5)*. Funding agencies are urged to make the necessary resources available for surveys that conform to these recommendations, in order to ensure the continuing collection of reliable, programme-ready data for trachoma elimination.

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