VALIDATION OF ELIMINATION OF TRACHOMA AS A PUBLIC HEALTH PROBLEM

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Terminology

10 In 1998, the Fifty-first World Health Assembly adopted resolution WHA51.11 on the global elimination of blinding trachoma.[1] For equivalent targets for other neglected tropical diseases, the term "elimination as a public health problem" has been adopted. For the sake of harmonization, the terminology now used for trachoma elimination is "elimination of trachoma as a public health problem", not "elimination of blinding trachoma".

20 In 2012, Oman became the first country to be recognized as having eliminated trachoma as a public health problem.[2] The process of assessment was referred to as a "verification" exercise. In 2015, the WHO Strategic and Technical Advisory Group on Neglected Tropical Diseases endorsed standardized processes for confirming and acknowledging success for all neglected tropical diseases targeted for eradication, elimination of transmission, or elimination as a public health problem.[3] The process for diseases targeted for elimination as a public health problem has been defined as "validation".

Use of these standard operating procedures

30 These standard operating procedures are intended to be used when a Member State wishes to request validation of national elimination of trachoma as a public health problem following implementation of the SAFE strategy,[1] which comprises: surgery for trachomatous trichiasis, antibiotics to clear infection, and facial cleanliness and environmental improvement to reduce transmission.

Technical indicators of elimination of trachoma as a public health problem

40 Elimination of trachoma as a public health problem is defined as: (i) a prevalence of trachomatous trichiasis (TT) "unknown to the health system" of < 1 case per 1000 total population; and (ii) a prevalence of trachomatous inflammation-follicular (TF) in children aged 1–9 years of < 5%, in each formerly endemic district.[4] Districts are defined as the normal administrative unit for health care management, which for the purposes of clarification consist of a population unit between 100 000 and 250 000 persons.[5] TT "unknown to the system" excludes TT in individuals with post-surgical recurrence, TT in individuals who have refused surgery, and TT in individuals who are listed for surgery but have not yet received an operation, but for whom a surgical date has been set.[5]

50 There must also be written evidence that the health system is able to identify and manage incident TT cases, using defined strategies, with evidence of appropriate financial resources to implement those strategies.[5]

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[1] Resolution WHA51.11. Global elimination of blinding trachoma. In: Fifty-first World Health Assembly, Geneva, 16 May 1998. Resolutions and decisions, annexes. Geneva: World Health Organization; 1998.

[2] Global Alliance for the Elimination of Blinding Trachoma by 2020: progress report on elimination of trachoma, 2012. Wkly Epidemiol Rec. 2013; 24:242–51.

[3] Generic framework for control, elimination and eradication of neglected tropical diseases. Geneva: World Health Organization; 2016 (WHO/HTM/NTD/2016.6).

[4] Report of the 2nd global scientific meeting on trachoma, Geneva, 25-27 August, 2003. Geneva: World Health Organization; 2003.

[5] Report of the 3rd global scientific meeting on trachoma, Johns Hopkins University, Baltimore, MA, 19-20 July 2010. Geneva: World Health Organization; 2010.

60 TT is rare in children, and becomes progressively more common with increasing age. In defining the elimination prevalence threshold for TT, the 2nd Global Scientific Meeting on Trachoma (Geneva, 25–27 August, 2003)[4] set out the following parameters and assumptions: (i) a TT prevalence of ≥ 1% in the population aged ≥ 15 years constitutes a public health problem; (ii) ≥ 10 cases per 1000 population aged ≥ 15 years is equivalent to ≥ 5 cases per 1000 total (all ages) population; and (iii) programmes should achieve an 80% relative reduction below the minimum level at which TT constitutes a public health problem. Because at baseline most national programmes estimate the prevalence of TT in adults aged ≥ 15 years,[6] when conducting impact and pre-validation surveillance surveys, it may be simpler and more epidemiologically relevant to again estimate the prevalence of TT in adults aged ≥ 15 years, rather than in the all-ages population. For the purposes of clarification, therefore, the elimination prevalence threshold for TT can also be expressed as < 0.2% in adults aged ≥ 15 years.

70 Establishing that the TT and TF prevalence thresholds have been met in a district is a two-step process. First, following a period of implementation of interventions against trachoma, and at least six months after the final planned round of antibiotic mass drug administration has been completed, an impact survey should be undertaken. If the TF prevalence threshold has been met, the district enters a two-year period of pre-validation surveillance, during which time antibiotic mass drug administration should not be implemented. Second, at the conclusion of that two-year period, a pre-validation surveillance survey should be undertaken.[7] Standard operating procedures for impact surveys and pre-validation surveillance surveys are provided separately.

80 A country meets the criteria for validation if all previously endemic districts demonstrate sub-elimination-threshold TT and TF prevalences in adequately-conducted pre-validation surveillance surveys, although consideration may also need to be given to the relative timing of intervention and surveillance activities in adjacent districts.

Preparation and submission of a dossier

90 The Member State should prepare a dossier documenting the achievement of elimination targets. Member States may request assistance from WHO to support the preparation of the dossier.

100 The dossier should contain the information requested in the template established by WHO.

110 The Member State should submit the completed dossier (one hard copy and one electronic copy) to the WHO Country Office. The Country Office should acknowledge receipt to the Member State, and forward the dossier to the trachoma focal point in the WHO Regional Office. The WHO Regional Office should notify the Department of Control of Neglected Tropical Diseases at WHO headquarters.

[6] Solomon AW, Pavluck A, Courtright P, Aboe A, Adamu L, Alemayehu W et al. The Global Trachoma Mapping Project: methodology of a 34-country population-based study. Ophthalmic Epidemiol. 2015; 22:214–25.

[7] WHO Strategic and Technical Advisory Group on Neglected Tropical Diseases. Technical consultation on trachoma surveillance, 11−12 September 2014, Task Force for Global Health, Decatur, USA. Geneva: World Health Organization; 2015 (WHO/HTM/NTD/2015.02).

Reviewing authority

120 The dossier will be assessed by an ad-hoc reviewing authority called the Dossier Review Group (hereinafter referred to as the Group). The Group's task is to evaluate the evidence of elimination of trachoma as a public health problem from the Member State, and recommend to WHO whether or not the claim should be validated.

130 The WHO Regional Office will be responsible for appointing the Group, having discussed and agreed its membership with the Department of Control of Neglected Tropical Diseases at WHO headquarters. The Group should comprise at least three members who meet the criteria below:

a. Some 2–3 experts on the SAFE strategy, at least one of whom should if possible be very knowledgeable about the implementation of SAFE interventions in the Member State under consideration; and 1–2 experts on the validation process for trachoma and/or analogous processes for other neglected tropical diseases.
b. Members should not be nationals of the Member State under consideration, work for the National Health Authority of the Member State under consideration, have been involved in implementation of the SAFE strategy in the Member State under consideration, or have supported the preparation of the dossier; such individuals can be invited to participate as observers.
c. Members will be invited to participate as individuals, not as representatives of an organization, institution or government. Nomination by members of proxies will therefore not be permitted.
d. In addition to the above, 1 delegate of the WHO Country Office; 1–2 delegates of the programme for control of neglected tropical diseases or prevention of blindness in the relevant WHO Regional Office; and 1 delegate of the Department of Control of Neglected Tropical Diseases at WHO headquarters will jointly act as Secretariat to the Group.

Review procedures

140 Members of the Group will elect a Chair from among their number. The Chair will be responsible for chairing Group meetings; considering requests made by the Secretariat for observers to join Group meetings; coordinating and completing, with other Group members, a report on the country visit (if it is deemed necessary) to the Member State, before Group members depart from the country; and signing off the summary report to WHO; in addition to the tasks asked of all Group members.

150 The scope of work for the Group is as follows:

a. A visit to the country will be undertaken for the purposes of the validation process only if there is a consensus of the Group that such a visit is required.
b. Members will examine dossiers on a voluntary basis, independently maintaining the highest ethical standards, and declaring any conflicts of interest prior to participation in collective discussions.
c. Members will provide written comments on the dossier to share with other members and shall clarify comments during collective discussions to facilitate development of a summary report.
d. Members will obtain consensus and recommend that WHO either (i) validates the claim of elimination as a public health problem; or (ii) postpones such a decision until more evidence is provided in the dossier to demonstrate that this has occurred. In either case, the recommendation must be adequately justified.

e. Members will also provide recommendations to the country: in case of validation, recommendations should focus on post-validation surveillance activities; in case of postponement, recommendations should focus on the steps that the country should take in order to successfully validate elimination of trachoma as a public health problem in the future.

160 The Secretariat will not seek to influence the Group's recommendations. It will:

a. Provide the dossier and other information needed to each Group member.
b. Obtain independent reviews of the dossier from each Group member.
c. Organize discussions of the Group via videoconference, teleconference or face-to-face meetings, inviting observers where this is considered desirable and agreed by the Group's Chair.
d. Provide clear direction about the responsibilities and decision-making processes of the Group.
e. Liaise with Member State authorities in order to obtain any additional information requested by the Group.
f. Organize the country visit (if deemed necessary), defining the terms of reference and agenda for the visit.
g. Collate the comments of Group members in a summary report.
h. Obtain sign-off of the summary report by the Group Chair.
i. Appropriately process and permanently archive the summary report.

170 Each Group member will:

a. Keep confidential the contents of the dossier and all other information to which Group members are given access, including the deliberations and recommendations of the Group, discussing them only with relevant WHO staff and other Group members. Information should not be discussed directly with the Ministry of Health of the Member State, or with any other organization or person.
b. Provide an independent review of the dossier within the timeframe and following the directions given for this task.
c. Collectively discuss the dossier, via video conference, teleconference or face-to-face meeting.
d. If deemed necessary, participate in a country visit.
e. Review the draft summary report within the timeframe given for this task.

Processing of recommendations

180 Following sign-off of the summary report by the Group Chair:

a. If the Group recommends validation of elimination of trachoma as a public health problem, the summary report will be forwarded by the WHO Regional Office to the Director, Department of Control of Neglected Tropical Diseases at WHO headquarters, who will notify the WHO Director-General.
b. If the Group recommends postponement of validation of elimination, the summary report will be forwarded by the WHO Regional Office to the Member State.
c. Where indicated, WHO headquarters will report the achievement of the Member State in the next annual disease-specific article published in the *Weekly Epidemiological Record*, and change the trachoma endemicity status of the Member State in the Global Health Observatory to "validated as having eliminated trachoma as a public health problem".

Timescale of review

190 Review of the dossier and (if deemed necessary) the country visit will be completed within six months of receipt of the dossier by the WHO Regional Office.

After validation

200 Validation is a reversible state, and all stakeholders should bear this in mind in their communications at all stages.

210 Countries should continue to conduct post-validation surveillance as recommended by the Group. A commitment to continue surveillance should be stated in the dossier. Surveillance data should be reported to WHO.

220 Where surveillance data indicate that disease or infection has reappeared or recrudesced, the WHO Department of Control of Neglected Tropical Diseases may be consulted on an appropriate response. Recrudescence above elimination target thresholds will be noted by a change in endemicity status in the Global Health Observatory and in the Weekly Epidemiological Record.

230 With the agreement of the Member State, once the WHO Director-General acknowledges that trachoma has been eliminated as a public health problem, the dossier may be made available on the WHO website as a reference document.

TEMPLATE FOR THE DOSSIER DOCUMENTING ELIMINATION OF TRACHOMA AS A PUBLIC HEALTH PROBLEM

This template dossier was designed to help managers of national trachoma programmes prepare a dossier with supporting evidence for presentation to WHO, requesting validation that trachoma has been eliminated as a public health problem. The information presented in the dossier will help reviewers understand programme achievements, by providing both epidemiological evidence and the broader context.

Sections of the template that are marked "required" are for information that must be included; sections that are marked "optional" may be completed or left blank, at the discretion of the national trachoma programme.

[Country]

Date of submission:

Date of review:

1. BACKGROUND

1.1 DEMOGRAPHIC AND DEVELOPMENT CONTEXT (OPTIONAL)

- *In narrative form,* summarize the demographic and economic features of the country, referencing the most recent census, Demographic and Health Survey, and/or other relevant documents, as desired. Describe the systems for delivery of WASH services, particularly to rural areas.

- It may be helpful to provide information and/or maps on poverty, infrastructure, and household access to water and sanitation.

1.2 HEALTH SYSTEM (OPTIONAL)

- *In narrative form*, provide an overview of the health system, describing:
    - the formal health system structure, including the delivery of primary healthcare services; and
    - the local epidemiology of any other endemic diseases that may be relevant to the actions of the trachoma programme.

1.3 TRACHOMA HISTORY (OPTIONAL)

- *In narrative form*, describe the history of the trachoma programme. This might include, for example:
    - a brief description of historical information about trachoma epidemiology in the country; and
    - a brief description of any interventions against trachoma prior to the launch of the current national trachoma programme.

1.4 TRACHOMA PROGRAMME OVERVIEW (REQUIRED)

- *In narrative form*, describe:
    - which organization established the trachoma programme, and in which year;
    - the internal structure of the trachoma programme, describing who or what takes responsibility for implementation of each component of the SAFE strategy;
    - whether or not the trachoma programme is integrated or coordinated with other public health programmes, with WASH programmes and/or with the education system; and if it is, how this is done; and
    - the data collection and management system used by the trachoma programme, focussing on how data from cross-sectional surveys (at baseline, impact and pre-validation surveillance stages) and data on implementation of each component of the SAFE strategy, are or were collected, aggregated and transmitted from community to national level.

2. DELINEATION OF AREAS REQUIRING INTERVENTION

2.1 DEFINITION OF EVALUATION UNITS (REQUIRED)

- *In narrative form:*
    - define the administrative units in the country ("states" and "districts", for example; going from largest units to the smallest units);
    - quantify the number of administrative units of each type; and
    - describe the basis for the formation of evaluation units (EUs) used, and whether this changed from baseline mapping to programme completion. Please include:
        - the number of EUs at the start of the programme — (a)

- the number of EUs at the end of the programme, or at the time of dossier submission — (b)
- an explanation of any changes that occurred to the number of EUs between (a) and (b) due to restructuring of administrative boundaries

2.2 DATA USED TO CLASSIFY EVALUATION UNITS (REQUIRED)

- *In narrative form*, describe*:*
  - the methods used to determine whether or not trachoma was a public health problem at baseline in each EU, including, for any surveys, the protocol followed and the sampling methodology; and
  - if the status of any EU (with respect to whether or not trachoma was a public health problem in it) was reassessed during the course of the programme, why and how the EU was reassessed.
- *In the accompanying data spreadsheet*, enter baseline survey data (where collected), for trichiasis (tab 1) and active trachoma (tab 2), for each EU.
- *Insert maps here* to display those data and identify areas that were determined not to need baseline surveys. One map should be used to display data on trichiasis (trichiasis prevalence categories, in adults: < 0.20%, 0.20–0.99%, 1.00–4.99%, ≥ 5.00%); one map should be used to display data on active trachoma (trachomatous inflammation—follicular prevalence categories, in children aged 1–9 years: < 5.0%, 5–9.9%, 10.0–29.9%, ≥ 30.0%).

3. IMPLEMENTATION OF SAFE INTERVENTIONS

3.1 SURGERY (REQUIRED)

- *In narrative form*, describe:
  - the selection, training and certification of trichiasis surgeons;
  - the indications, contraindications and techniques used for trichiasis surgery;
  - the indications, contraindications and methods used for any non-surgical management of trichiasis;
  - the methods used for case-finding of individuals with trichiasis;
  - the modes of delivery of trichiasis surgery (fixed site, surgical camps, mobile teams);
  - whether adjunctive antibiotics were routinely given at the time of trichiasis surgery;
  - the in-service supervision of trichiasis surgeons;
  - the routine follow-up of operated patients; and
  - any surgical audits performed as part of the programme.
- *In the accompanying data spreadsheet*, on tab 1, enter data, for each programme year, on the number of people (not the number of eyes) given operations for trichiasis in each EU.

3.2 ANTIBIOTICS (REQUIRED)

- *In narrative form*, describe:
  - the antibiotic regimens used for community-level interventions against trachoma;
  - the indications and contraindications for the use of those antibiotics;
  - the methods used for community sensitization and antibiotic distribution; and
  - any serious problems encountered when offering antibiotics, particularly widespread refusal or serious adverse events.
- *In the accompanying data spreadsheet*, on tab 2, enter data, for each programme year, on the number of people given antibiotics, and the antibiotic coverage, in each EU.

3.3 FACIAL CLEANLINESS (REQUIRED)

- *In narrative form*, describe:
    - the channels, messages and materials used to promote facial cleanliness;
    - for each type of activity intended to promote facial cleanliness, its frequency of implementation; coverage or scale of implementation; setting (e.g. school, or community during antibiotic mass drug administration); and target audience (e.g. mothers of preschool-aged children, or school-aged children);
    - the types of personnel used to undertake promotion of facial cleanliness; and
    - the training and supervision of personnel undertaking promotion of facial cleanliness.

  For each type of personnel, include details on frequency of training and supervision, and who was responsible for delivering training and supervision.

  Describe all activities intended to promote facial cleanliness, whether undertaken by the trachoma programme, by trachoma programme partners or by other programmes (e.g. as part of broader hygiene promotion initiatives).

- *In the accompanying data spreadsheet*, on tab 2, identify, for each trachoma programme year, which facial cleanliness activities were delivered in each EU.

3.4 ENVIRONMENTAL IMPROVEMENT (REQUIRED)

- *In narrative form*, describe:
    - the activities undertaken to improve water availability in trachoma-endemic populations, including their intensity, scale, and the agencies responsible for delivery;
    - the activities undertaken to improve access to sanitation in trachoma-endemic populations, including their intensity, scale, and the agencies responsible for delivery; and
    - whether there were any coordination or collaboration mechanisms between the trachoma programme and other WASH programmes?

- *In the accompanying data spreadsheet*, on tab 2, identify, for each trachoma programme year, which environmental improvement interventions were delivered in each EU.

4. IMPACT AND PRE-VALIDATION SURVEILLANCE SURVEYS

4.1 IMPACT SURVEYS (REQUIRED)

- *In narrative form*, describe*:*
    - the timing and methods used for impact surveys, including the protocol followed and sampling methodology.
- *In the accompanying data spreadsheet*, enter impact survey data, for trichiasis (tab 1) and active trachoma (tab 2), for each EU.

4.2 PRE-VALIDATION SURVEILLANCE SURVEYS (REQUIRED)

- *In narrative form*, describe*:*
    - the timing and methods used for pre-validation surveillance surveys, including, for any surveys, the protocol followed and sampling methodology.
- *In the accompanying data spreadsheet*, enter pre-validation surveillance survey data, for trichiasis (tab 1) and active trachoma (tab 2), for each EU.
- *Insert maps here* to display those data.

4.3 REGIONAL CONTEXT (REQUIRED)

- *In narrative form,* briefly describe the current epidemiology of trachoma in bordering countries, and comment on whether the disease in those countries is considered to present a risk to the achievements of your programme. (Trachoma prevalence data can be found at the Trachoma Atlas: www.trachomaatlas.org)
- If possible, *in the maps requested in section 4.2*, display data on the current epidemiology of trachoma in bordering countries.

5. POST-VALIDATION SURVEILLANCE (REQUIRED)

- *In narrative form,* describe:
    - national plans (if any) for post-validation trachoma surveillance;
    - national plans for provision of TT surgical services until there are no longer any incident cases of TT; and
    - national plans for continued Ministry of Health engagement with other government ministries and partners responsible for the provision of WASH services, to ensure prioritization of EUs with the lowest levels of WASH service access.

6. SPECIAL ISSUES (OPTIONAL)

- *In narrative form*, describe:
    - any special circumstances that have affected the programme; these could include, but are not limited to:
        i. stability or security issues in the country; and/or
        ii. immigration from other trachoma-endemic countries.
    - any specific efforts to investigate trachoma prevalence and/or intervention coverage in difficult-to-reach populations (e.g. nomadic peoples, internally displaced persons, or refugees).

7. RESOURCES AND PARTNERSHIPS (OPTIONAL)

- *In narrative form*:
    - briefly describe the human resources employed to implement the programme; and
    - estimate internal and external financial resources utilized for the programme.
- *Complete the following table*, listing the partners of the programme:

Table 7.1. Partners of the trachoma elimination programme, [Country]

Partner name	Nature of support	Geographical areas of support	Year support started	Year support ended
e.g. Foundation X	*Financial support for trichiasis surgery*	*Regions A and C*		

8. BIBLIOGRAPHY (REQUIRED)

- *Insert here* a bibliography of all data sources used to develop this dossier, including:
    - Ministry of Health records
    - published papers
    - academic theses and dissertations

  Copies of unpublished documents may be requested by WHO.

9. ABBREVIATIONS (REQUIRED)

- *Insert here* a list of all abbreviations used in the dossier, with their definitions.