

REPORT OF THE 3rd GLOBAL SCIENTIFIC MEETING ON TRACHOMA

BALTIMORE, USA

19-20 JULY, 2010

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1. Introduction

Trachoma continues to be the leading infectious cause of blindness world –wide. The World Health Organization has taken a central role in coordinating international efforts to eliminate blinding trachoma, beginning with the first Global Scientific Meeting in 1996 to identify approaches for trachoma control. This meeting set the technical framework for the activities of the WHO Alliance for the Global Elimination of Trachoma by 2020 (further referred as WHO GET2020). In 1998, the World Health Assembly passed a resolution calling for the elimination of blinding trachoma as a public health problem by 2020, and recommended increased activities in support of that goal (resolution WHA51.11, 16/5/1998)

Since that time, increasing numbers of Member States have reported on trachoma control activities at the annual meeting for the WHO GET2020. By 2000, it became clear that the partners of the Alliance needed technical tools to set goals and monitor progress. In addition, national programmes were beginning to implement the SAFE strategy and conduct outcome surveys at different time points, with no overall guidelines. Finally, a new assessment of the global burden of trachoma was sorely needed in order to plan for the work ahead. Thus, the Programme for the Prevention of Blindness and Deafness convened a second Global Scientific Meeting on Trachoma in 2003.

The goals of the second Global Scientific Meeting were: to re-assess the global and regional burden of trachoma, basing estimates on the available data, to review the list of endemic countries, to define the Ultimate Intervention Goals (UIG) for trachoma, and to develop a methodology to identify them in endemic countries. The report from the meeting provided an estimate of 84 million persons with active trachoma and 7.6 million persons with trachomatous trichiasis. Regional estimates proved difficult without more recent and reliable data from China and India. The report from the second GSM also developed UIGs and provided methodologies for identifying them in endemic countries. This is critical background information for the subsequent meeting, and will be summarized in this report.

With the advent of increasing numbers of countries on target to achieve elimination of blinding trachoma, WHO recognized the need to clarify the existing definition of elimination and clarify as well what might be considered as sufficient evidence of elimination in case certification from W.H.O. is sought. Several reports that summarized lessons from other disease campaigns and suggestions for indicators were presented, reviewed and discussed. At least two informal working groups were convened, notably in 2005 in Baltimore, to define optimal criteria for the development of guidelines on elimination. Such guidelines for elimination of trachoma will be developed by WHO following the current official procedures. In order to facilitate this the informal working groups were charged with developing the scientific evidence and rationale to expedite the approval of guidelines, the case definitions, the possible classification scheme for countries, and possible documentation that could be used towards certification.

By 2009, more countries were on target to cease mass drug administration programs for active trachoma control in some regions, and identified a need for further clarification of steps as they approached reaching the UIG for active trachoma. At the meeting of the WHO GET2020 in 2009, Member States and their international partners expressed a strong need for WHO to review new evidence from operational research and revisit some of the previous recommendations with a goal for updating and clarifying some discrepancies. The secretariat of the WHO GET2020 Alliance, therefore convened the third Global Scientific Meeting on Trachoma Elimination, held in the Johns Hopkins University, Baltimore Maryland on July 19-20th 2010.

The review of recent data and programme experience was designed to consider issues of revisiting and refining the targets, the assessment methods, and the requirements previously defined for elimination. The purpose of the meeting was to determine if new evidence may lead to refinement of previous global scientific meeting and working group conclusions and recommendations, as follows (see Annex 2):

- $1. \ \ to \ review \ current \ recommendations \ and \ treatment \ directives \ for \ MDA \ and \ targeted \ treatment$
- 2. to clarify previous recommendations on certification of elimination of blinding trachoma, considering each component of the SAFE strategy.

a. Opening of the Meeting

The meeting was opened by Dr Silvio P. Mariotti, Secretary and Coordinator of the WHO GET2020 Alliance, who reviewed the scope and purpose of the meeting and set the institutional framework for the work of the participants. Dr Alfred Sommer, former Dean of the Johns Hopkins Bloomberg School of Public Health and Director of the Dana Center for Preventive Ophthalmology officially welcomed all participants to Johns Hopkins University, and emphasized the critical importance of providing clear guidelines, in a public health framework, for determination of elimination of blinding trachoma.

b. Officers and agenda

After introduction of all participants, Dr Eric Ottesen and Dr Thomas Lietman agreed to serve as chair and vice chair of the meeting. Dr Sheila West agreed to serve as rapporteur. The list of participants is in Annex 1. The agenda was adopted with no amendment (Annex 3).

2. Monitoring and Evaluation

Definitions:

The meeting participants used the following definitions, derived from the second GSM meeting, which were further refined during the meeting.

- 1. District: A district is defined as the administrative unit for health care management and for purposes of clarification consists of a population unit between 100,000-250,000 persons.
- 2. Sub-district: a geographic or other grouping of at least three villages that permits finer stratification of a district into sub units that might be expected to have greater or lesser prevalence of trachoma.
- 3. Village: a population unit of 8,000-10,000 persons.
- 4. Community: A defined group of households, a village, or a group of neighboring villages, for which mass trachoma control activities can be implemented. A community may be as large as a sub district or may be smaller than a village.

Monitoring for UIG

The UIG for AFE is: TF is less than 5% in children 1-9 years of age in a district or community (2nd WHO GSM page 15). The previous recommendation from the 2nd GSM for the strategy to achieve the UIG is the following (2nd WHO GSM page 15):

- 1. If TF prevalence is >10% in children 1-9 years old at district or community level, initially conduct mass treatment with antibiotic, (azithromycin and/or tetracycline eye ointment) for a minimum of three years before re-assessing the situation and not stopping Mass Drug Administration (MDA) until TF in 1-9 year olds is <5% at community level.
- 2. Aim for coverage at the community level of at least 80% of the eligible population (can be considered equal to the total population), and conduct hygiene promotion and environmental improvement to achieve 80% of children in the community with clean faces.
- 3. After three years, resurvey the population for TF and decide whether "A" is still indicated.

The participants reviewed data available from several programmes and projects implementing MDA with azithromycin showing that when communities start with prevalence of active trachoma (TF prevalence in 1-9 y.o.) greater than 30% at baseline, even with coverage higher than 90%, in no study or treatment setting the prevalence was below 5% (or even 10%) after three years of consecutive MDA.

Consensus:

- 1. If TF is >10% in 1 to 9 year olds at baseline, it is not necessary to re-survey to guide program decisions <u>before at least three years of "AFE" implementation</u>.
- 2. In districts where the baseline prevalence is high (consensus suggested at least 30%) it is not necessary to do outcome surveys before 5 years of "AFE" implementation.
- 3. National programs should aim for 100% coverage with "AFE" interventions and plan for sufficient antibiotic supply during the year of the outcome survey so as not to have an interruption of treatment if MDA is still warranted.

3. Survey Methodology

Program Start-up

Participants reviewed different survey methodology for different aims. Population-based data are essential for program start up. "Purposeful" sampling (selecting districts or communities where trachoma was suspected to be most highly endemic, as is done in the Trachoma Rapid Assessment methodology) can be used at the start, provided the estimates of trachoma are then based on some form of random sampling to enable population-based estimates. For countries just starting a new trachoma control program, or countries wishing to start a program in new areas of the country, the following consensus recommendations were made.

Consensus

- 1. For new countries/new areas starting a program, population-based data are necessary for planning. District level data is the gold standard, but village level data can be used IF they are not extrapolated to represent the prevalence of an entire district
- 2. Larger geographical areas (e.g., regional) data can be used to start a program if the evidence shows that trachoma is widespread and highly endemic. However, if the estimate of TF for this large area is less than 10% in 1-9 year olds, then district level data must be obtained before starting a treatment programme.

Outcome Surveys

Outcome surveys are used to assess current status following the implementation of AFE. The following consensus recommendations were made:

Consensus

- 1. Outcome surveys must be conducted at the district level, not at larger aggregates (a district is the maximum population size for outcome surveys, see other recommendations on guidelines for stopping MDA)
- 2. Outcome surveys can be used to pronounce achievement of UIG for TF, if the sample size is powered to calculate estimates at the sub-district level

4. TF Indicator for Elimination

The 2005 working group proposed that countries be eligible for certification of elimination of blinding trachoma when they have achieved sustained reduction of follicular trachoma to <5% in children ages 1-9 years in the administrative unit selected for intervention for at least three years following cessation of a control program with antibiotic MDA. The participants reviewed the guidelines for stopping mass drug administration, and declaring elimination of active trachoma (defined as TF, graded using the WHO Simplified Grading System), in order to clarify confusion surrounding the population unit at which surveys must be conducted.

The participants considered data from hypo endemic countries, like The Gambia, where once the districts reported active trachoma prevalence to be below 5% there was no infection (as detected by nucleic acid amplification test) at village level. The few villages with trachoma (TF) that were above 10% prevalence were observed to have declining prevalence over time. Data from a village where there was a re-introduction of infection from Senegal showed that after 6 months, transmission was not sustained and infection disappeared. This is consistent with a model for a hypoendemic region where trachoma is disappearing, and although the distribution of disease has a tail of villages above 10%, the prevalences are declining.

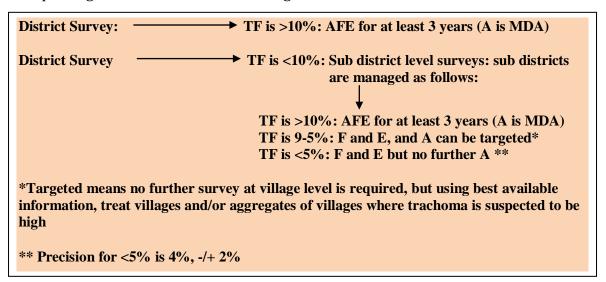
There was general consensus that not every village needed to be surveyed to declare elimination of blinding trachoma as a public health problem (WHA51.11), although participants could not determine any simple way to be certain of uncovering any few remaining villages that may still have a high prevalence of active trachoma. Review of the data suggested such villages, where the district or sub-district prevalence of TF is less than 5%, are the tail of the decline and trachoma is disappearing in any case. The following recommendations were agreed to by an overwhelming majority of the participants

Consensus

- 1. If the estimate of district prevalence of TF is below 10% in children 1-9 years old, then active trachoma must be assessed at the level of the sub district, or at village level. The district should be stratified into sub-units that are more homogenous for trachoma. The stratification can be based on knowledge of higher versus lower rates of trachoma at the start of the program, or geographical information such as clustering of villages around "hotspots" (villages proven to have high rates of trachoma), or that had presence or absence of water resources or other infrastructure that might indicate differing rates of trachoma. These sub-units or sub districts are an aggregate of at least three villages, and the sub units together make up the district.
- 2. If TF rates at the sub district level are 10% or higher in 1-9 year olds, then MDA in the whole sub-district, plus F and E, must be continued for at least three years and not stopped until trachoma is below 10%.

- 3. If TF rates at the sub district level are between 9% and 5% in 1-9 year olds, then F and E can be continued, but MDA is no longer necessary and targeted treatment can be considered. In this case, targeted treatment means using the best available data to treat villages or aggregates of villages within the sub-unit. However, no additional survey is needed for targeted treatment.
- 4. If TF rates at the sub district level are <5% in 1-9 year olds, F and E can be continued but no further antibiotic is needed. Family based treatment can be considered, using local knowledge that may be present in the treatment teams. The precision required for the estimate of "TF less than 5%" is allowed to be 4%, with a confidence interval of 2% $(4\%\pm2\%)$.

This paradigm is shown below in the diagram.



5. Surgery/TT Indicators for Elimination

The participants reviewed the previous recommendation for elimination based on surgery/TT, which is as follows:

Satisfactory implementation of a program to reduce the prevalence of trachomatous trichiasis through identification and surgical management through the health system, with a commitment to reach the Ultimate Intervention Goal of less than 1 case of TT (refusals, recurrences, and incident cases) per 1,000 population. (Working Group Document, 2005). However, it appears that the surgery component of SAFE has been neglected in recent national programmes reports, with considerable fall off in numbers of surgeries carried out. Concern was expressed that, although the UIG for surgery is clear, the previous recommendation for elimination was insufficient in assuring the UIG would be met.

Consensus

Countries will be eligible for consideration of having eliminated trachoma as a public health problem when they have achieved the following goal for TT: at district level, < 1/1,000 total population of trichiasis cases <u>unknown</u> to the health system.

Known cases of TT include recurrent cases and cases who have refused surgery, which must be recorded as part of the surgical information system. Cases who are listed for surgery but not yet operated are also classified as "known" if the delay is for logistic reasons but a surgical date is set. Furthermore, there must be evidence that the health system is able to identify and to manage incident trachomatous trichiasis cases, using defined strategies, with evidence of appropriate financial resources to implement these strategies.

In the strategy for achieving this goal, country programs must report a recurrence rate as part of the health information system, with a target of achieving 10% or less recurrence at one year after surgery.

6. F and E Indicators for Elimination

The participants reviewed previous reports on use of possible F and E indicators.

Consensus:

There is no recommendation about the use of F and E indicators for the assessment of elimination.

7. Next Steps

The group also discussed possible next steps, and the following were mentioned:

- 1. While criteria for elimination of TF were defined, some members of the group felt that further research is warranted to identify assessment strategies to find villages with high prevalences of TF in sub-districts where the estimated prevalence of TF is <5% in 1-9 year olds.
- 2. The group recommended that this report be made public as soon as possible to guide countries and implementing partners towards the goals of elimination. This is especially urgent as a more stringent criterion for TT is now being recommended.

Dr Mariotti expressed his appreciation to all the participants for their hard work and impassioned input. He declared the meeting closed

Annex 1: List of Experts

Dr Silvio P Mariotti, World Health Organization

Dr Simona Minchiotti, World Health Organization

Dr. Hugh Taylor, University of Melbourne

Dr Paul Emerson, The Carter Center

Dr Danny Haddad, International Trachoma Initiative

Dr Tom Lietman, Proctor Foundation, University of California San Francisco

Dr Robin Bailey, London School of Hygiene and Tropical Medicine

Dr Wondu Alemayehu, public health consultant, Ethiopia

Ms Beatriz Munoz, Dana Center for Preventive Ophthalmology, Johns Hopkins University

Dr Amza Abdou, Université Abdou Moumouni de Niamey, director PNLCC

Chair: Dr Eric Ottesen, Task Force for Child Survival.

Rapporteur: Dr Sheila West, Dana Center for Preventive Ophthalmology, Johns Hopkins

University

Annex 2: Scope and Purpose

The Certification of Elimination of trachoma is a high level formal act of public health in which the World Health Organization certifies that a Member State has achieved a goal set by the World Health Assembly; the procedures for issuing the Certification of elimination of trachoma are almost completed, but before finalizing them a review of recent data relevant to trachoma elimination is warranted. The review will consider issues of revisiting and refining the targets, the assessment methods, and language previously defined for certification.

Purpose: To review the most recent data from research and elimination programmes to identify if new evidence may lead to refinement of previous global scientific meeting conclusions.

- -To review current recommendations and treatment directives for MDA and clinical care
- -To clarify previous recommendations on certification of elimination of blinding trachoma, considering the whole aspects of the SAFE strategy

Outputs: Report to WHO/PBD-GET2020 secretary within three weeks from the end of the meeting

Annex 3: Agenda

WHO/PBD-GET2020 Global Scientific Meeting on Trachoma elimination

Agenda Smith Building, Wilmer Eye Institute 5th Floor Conference Room July 19-21, 2010

DAY ONE 8:30-8:40 Welcome: Dean Emeritus and former director, Dana Center, Dr Alfred Sommer 8:40-8:45 Administrative details: Drs Mariotti and West 8:45 Mapping, Monitoring and Evaluation: interim Chair: Tom Lietman a. Current recommendations: If TF in 1 to 9 y.o.>10% do three MDAs at > 80% <u>coverage before re-survey:</u> Review new data and refine previous directives 8:45-9:15 Presentation of data (10 minutes each) a. Hypo endemic areas: RB b. Mesoendemic area: SW c. Hyper endemic areas: TL 9:15-10:30 Discussion: Refine recommendations based on presented evidence 3 MDAs and resurvey? Role of coverage? 10:30-11:00 Coffee break 11:00 b. Review and Refine, Survey methodology for different aims: Chair: Eric Ottesen 1. For new countries just starting a program, TRA can prioritize districts in hyperendemic areas where all will likely eventually be covered. 11:00-11:20 Presentation of Data: (ten minutes each) a. Can we use TRA to start a program: Pacific Islands: HRT b. Do we need CRS, prevalence survey, at outset? Ethiopia (region estimates) vs. Sudan (district estimates); PE 11:20-12:30 Discussion: Refine recommendations Data needed to start a trachoma program of SAFE 12:30-1:30 Lunch in conference room

1:30	2. For Outcome surveys to assess current status (no existing guidelines)
1:30-2:20	Presentation of data (ten minutes each) a. Methods for surveys on SAFE: Carter Center experience: PE b. Ghana experience on district at <5%: PE c. Evidence from The Gambia on district <5%: RB d. Evidence form Nepal, models of trachoma disappearing: TL e. how many clusters are enough for CRS?: BM
2:20-3:30	Discussion and draft recommendations Outcome surveys: can these be used to pronounce achievement of TF/ TT UIG? (Issue of <5% at district in outcome survey, versus community surveys to pronounce UIG achievement)
3:30-4:00	Coffee break
4:00-5:00	Continue discussions and refine recommendations, based on evidence
5:00	Adjourn:
DAY TWO	
(Chair, Rappo recommenda	orteur and WHO secretariat meet 7:30-8:30 at meeting room to draft tions)
8:30-9:30	Review previous day's recommendations and refine: Chair and Rapporteur
9:30-11:20	For validation of Elimination-3 years after UIG is achieved: Several methodologies for surveys of active trachoma exist, and no single method should be selected as the only approach. Countries can choose the method most appropriate for their needs. (Working Group on Guidelines for Elimination)
9:30-9:50	Presentation of data (ten minutes each) a. Review of previous recommendation: SW b. Lessons from other NTDs: EO
9:50 -10:20	Coffee break
10:20-11:20	Discussion and refinement of recommendations
11:20	Revisit Elimination criteria for " <u>Blinding</u> Trachoma" Countries will be eligible for certification of elimination when they have achieved the following goals:

1. Sustained reduction of follicular trachoma to 5% in children ages 1-9 in an administrative unit (the smallest implementation for a country) for at least three years following the cessation of a vertical control program with antibiotic distribution.

This goal reflects the Ultimate Intervention Goal target of reduction of prevalence of TF to 5% in children age 1-9; the goal adds the element of a sustained reduction, in the absence of vertical treatment programs, to ensure that active trachoma is unlikely to re-emerge. (Working Group Document, 2005)

NOTE: This document also contains the following statement: Countries which WHO currently considers to have endemic trachoma are ones in which at least one district has at least one community with a prevalence of active trachoma in children age 1-9 that exceeds 5%, and trichiasis above 1/1,000.

- 11:20-11:30 Review elimination criteria from previous meetings, and indicators (SM)
- 11:30-12:00 Data on correspondence of district level prevalences with village level prevalences (10 minutes each)

The Gambia (RB) Ghana (PE) Nepal (TL)

- 12:00-1:00 Lunch
- 1:00-2:30 Discussion and Refinement of Recommendations and definition of population unit in terms of blinding trachoma
- 2:30-3:00 Summarize recommendations
- 3:00-3:30 Coffee break
- 3:30-4:30 Surgery (UIG for trichiasis), F and E: Indicators for elimination Recommendation for S: 2. Satisfactory implementation of a program to reduce the prevalence of trichiasis through identification and surgical management through the health system, with a commitment to reach the Ultimate Intervention Goal of less than 1 case of TT (refusals, recurrences, and incident cases) per 1,000 population. (Working Group Document, 2005). No recommendation for F and E indicators
- 3:30-4:30 Discussion and refinement of recommendation, if needed
- 4:30-5:00 Summarize recommendations
- 5:00 Adjourn

DAY THREE

(Chair, Rapporteur and WHO secretariat meet 7:30-8:30 at meeting room to draft recommendations from Day 2)

8:30-10:00 Review previous day's recommendations and refine: Chair and Rapporteur

10:00-10:30 Coffee break

10:30-11:30 Discussion: Clarification of activities at TF between >5% and <10%: District vs Community

a. S, F and E only?

b. Need to hunt communities which may be above 10%? Hunt for families?

c. Draft refinement if needed

11:30-12:00 Review Day three recommendations

12:00 Adjourn meeting

Definitions of terms

Output: The immediate products which result from an intervention; may also include changes resulting from the intervention which are relevant to the achievement of outcomes.

Outcome: The likely or achieved <u>short-term and medium-term</u> effects of an intervention's outputs. Outcomes are the observable behavioral, institutional and societal changes that take place over 3 to 10 years, usually as the result of coordinated short-term investments in individual and organizational capacity building for key development stakeholders (such as national governments, civil society, and the private sector).

Impact: Positive and negative, primary and secondary <u>long-term effects</u> produced by a development intervention, directly or indirectly, intended or unintended.